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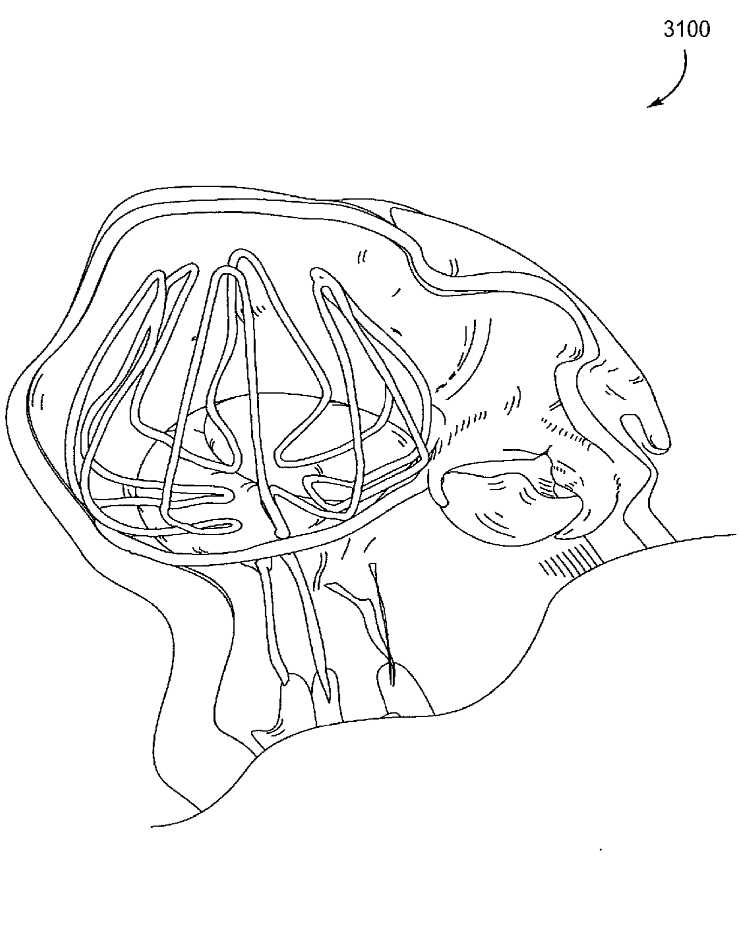

(57) Abstract: The present invention is a group of medical devices designed to improve heart valve function. The medical devices may be used individually, or in combination to supplement damaged valves, replace damaged valves, or improve damaged valves function. The medical devices include leaflet retainers, a neo-annulus, neo-leaflet, and a framework. In addition, the present invention is novel methods for surgically treating heart valves.

WO 03/028558 A2

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METHODS AND DEVICES FOR HEART VALVE TREATMENTS

REFERENCE TO PENDING PRIOR PATENT APPLICATION

This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial Number 60/326,590 filed October 1, 2001 by John A. Macoviak, which patent is hereby incorporated by reference.

FIELD OF THE INVENTION

This invention relates to methods and devices to improve the function of heart valves. More particularly, the invention relates to methods and devices to treat mitral valve regurgitation.

BACKGROUND OF THE INVENTION

The opening and closing of heart valves occur primarily as a result of pressure differences. For example, the opening and closing of the mitral valve occurs as a result of the pressure differences between the left atrium and the left ventricle. During ventricular diastole, when ventricles are relaxed, the venous return of blood from the pulmonary veins into the left atrium causes the pressure in the atrium to exceed that in the ventricle. As a result, the mitral valve opens, allowing blood to enter the ventricle. As the ventricle contracts during ventricular systole, the intraventricular pressure rises above the pressure in the atrium and pushes the mitral valve shut.

The high pressure produced by contraction of the ventricle could push the valve leaflets too much and evert them. Prolapse is a term used to describe this condition. This is normally prevented by contraction of the papillary muscles within the ventricle, which are connected to the mitral valve leaflets by the chordae tendineae (chords). Contraction of the papillary muscles is simultaneous with the contraction of the ventricle and serves to keep healthy valve leaflets tightly shut at peak contraction pressures exerted by the ventricle.

Valve malfunction can result from the chords becoming stretched, and in some cases tearing. When a chord tears, the result is a flailed leaflet. Also, a normally structured valve may

not function properly because of an enlargement of the valve annulus. This condition is referred to as a dilation of the annulus and generally results from heart muscle failure. In addition, the valve may be defective at birth or because of an acquired disease.

SUMMARY OF THE INVENTION

The present invention is a group of medical devices designed to improve heart valve function. The medical devices may be used individually, or in combination to supplement damaged valves, replace damaged valves, or improve damaged valves function. The medical devices include leaflet retainers, a neo-annulus, neo-leaflet, and a framework. In addition, the present invention includes novel methods for surgically treating heart valves.

BRIEF DESCRIPTION OF THE DRAWINS

Figure 1 shows a posterior oblique cutaway view of a patient's heart 100.

Figure 2 shows a cutaway view of a patient's heart 200 with a prolapsed mitral valve that does not form a tight seal during ventricular systole, and thus allows blood to be regurgitated back into the left atrium during ventricular contraction.

Figure 3 shows a cutaway view of a patient's heart 300 with a flailing mitral valve 320 that does not form a tight seal during ventricular systole, and thus allows blood to be regurgitated back into the left atrium during ventricular contraction as indicated by arrows.

Figure 4 shows a perspective view of a spring bridge neo-leaflet used to supplement or replace a native leaflet.

Figure 5 shows a perspective view of an embodiment of the invention comprised of a bridge 540, spanning material 530, attachment means 550, and a base 520. In addition, the device is shown to have a framework 510.

Figure 6 shows a perspective view of the embodiment of Figure 5 in the open valve position.

Figure 7 shows a perspective view of the embodiments shown in Figures 5 and 6 positioned within the left atrium of the heart.

Figures 8 and 9 show a perspective view of the embodiments of Figures 5 and 6 positioned within the left atrium of the heart.

Figure 10 shows a perspective view of an embodiment of the invention having a framework 1010 that avoids the pulmonary veins (not shown).

Figures 11 and 12 show a perspective view of a dual spring bridge neo-leaflet having an anterior bridge spanned by an anterior material 1110, and a posterior bridge spanned by a posterior material 1120.

Figure 13 shows a perspective view of a damaged native anterior leaflet 1310 that is not connected to the chordae tendineae.

Figure 14 shows a perspective view of a device 1400 having a half sewing ring 1420 with a membrane 1410 that serves as a neo-annulus or a neo-leaflet.

Figure 15 shows a perspective view of a device 1500 having a full sewing ring 1530 with a membrane 1510 that serves as a neo-annulus or a neo-leaflet.

Figure 16 shows a perspective view of a leaflet retainer 1600 that is positioned within the atrium on top of both native mitral valve leaflets.

Figure 17 shows a perspective view of a leaflet retainer 1700 that is positioned within the atrium on top of both native mitral valve leaflets.

Figure 18 shows a perspective view of a leaflet retainer 1800 that is positioned within the atrium on top of both native mitral valve leaflets.

Figure 19 shows a perspective view of a leaflet retainer 1900 that is positioned on top of both native mitral valve leaflets.

Figure 20 shows a side view of the embodiment shown in Figure 19.

Figure 21 shows a perspective view of the embodiment shown in Figure 19.

Figure 22 through 26 show the sequence of steps for a catheter-based percutaneous deployment of an embodiment of the invention.

Figure 27 shows a perspective view of an embodiment of the invention 2700 having a framework that partially fills the atrium.

Figure 28 shows a perspective view of an embodiment of the invention 2800 having dual neo-leaflets, 2830 and 2840.

Figure 29 shows a perspective view of an embodiment of the invention 2900 having a leaflet retainer 2910 positioned against a native leaflet as well as a framework structure 2920 that meanders about the atrium without interfering with the pulmonary veins.

Figure 30 shows a perspective view of another embodiment of the invention 3000 consisting of a continuous wire or tube that forms a leaflet retainer and framework.

Figure 31 shows a perspective view of a tulip shaped wire form configuration 3100 of the invention.

Figure 32 shows cutaway view of a tulip shaped wire form configuration 3200 of the invention.

Figure 33 shows a cutaway view of a tulip with a twist wire form configuration 3300 of the invention.

Figure 34 shows a cutaway view of the left atrium and left ventricle. The arrows on the left side of the figure indicate by way of example three different ways in which an embodiment of the invention, such as a leaflet retainer, neo-leaflet, or neo-annulus, may interact with the mitral valve, or be positioned if replacing a leaflet.

Figure 35 shows a perspective view of mesh leaflet with buttressing 3500.

Figure 36 shows a side view of a corona configuration 3600 of the invention.

Figure 37 shows a perspective view of a corona configuration 3700 of the invention *in situ* within a patient's left atrium.

Figure 38 shows a cutaway view of a heart, having both native leaflets, 3810 and 3820, intact.

Figure 39 shows a cutaway view of a heart with one embodiment of the invention 3900.

Figure 40 shows a cutaway view of a heart with one intact mitral valve leaflet 4010, and one mitral valve leaflet excised, or missing.

Figure 41 shows a cutaway view of a heart with one embodiment of the invention 4100. In addition, the shown embodiment has one neo-leaflet 4110.

Figure 42 shows a cutaway view of a heart with both mitral valve leaflets removed.

Figure 43 shows a cutaway view of a heart with one embodiment of the invention 4300 having two neo-leaflets.

DETAILED DESCRIPTION

Figure 1 shows a posterior oblique cutaway view of a patient's heart 100. Two of the four heart chambers are shown, the left atrium 170, and the left ventricle 140 (not shown are the right atrium and right ventricle). The left atrium 170 fills with blood from the pulmonary veins. The blood then passes through the mitral valve (also known as the bicuspid valve, and more generally known as an atrioventricular valve) during ventricular diastole and into the left ventricle 140. During ventricular systole, the blood is then ejected out of the left ventricle 140

through the aortic valve 150 and into the aorta 160. At this time, the mitral valve should be shut so that blood is not regurgitated back into the left atrium. The mitral valve consists of two leaflets, an anterior leaflet 110, and a posterior leaflet 115, attached to chordae tendineae 120 (hereafter, chords), which in turn are connected to papillary muscles 130 within the left atrium 140. Typically, the mitral valve has a D-shaped anterior leaflet 110 oriented toward the aortic valve, with a crescent shaped posterior leaflet 115. The leaflets intersect with the atrium 170 at the mitral annulus 190.

Figure 2 shows a cutaway view of a patient's heart 200 with a prolapsed mitral valve that does not form a tight seal during ventricular systole, and thus allows blood to be regurgitated back into the left atrium during ventricular contraction. The anterior 220 and posterior 225 leaflets are shown being blown into the left atrium with arrows indicating the direction of regurgitant flow. Among other causes, regurgitation can result from stretched chords 210 that are too long to prevent the leaflets from being blown into the atrium. As a result, the leaflets do not form a tight seal and blood is regurgitated into the atrium.

Figure 3 shows a cutaway view of a patient's heart 300 with a flailing mitral valve 320 that does not form a tight seal during ventricular systole, and thus allows blood to be regurgitated back into the left atrium during ventricular contraction as indicated by arrows. Among other causes, regurgitation can result from torn chords 310.

Figure 4 shows a perspective view of a spring bridge neo-leaflet used to supplement or replace a native leaflet. The device 400 is shown to be formed of a base 420 that is positioned around the mitral annulus, and then closes in over the anterior leaflet to form a bridge 430 over the anterior leaflet. The bridge 430 may be a rigid, semi-rigid, or flexible. The bridge may act like a spring, and thus respond dynamically to pressure differentials within the heart. The bridge 430 may have a spanning material 410 that spans the bridge 430. The spanning material 410 may be attached to the device 400 with one or more attachment means 440 (for example, it may be sewn, glued, or welded to the device 400, or it may be attached to itself when wrapped around the device 400). The spanning material 410 may be made from a synthetic material (for example, thin Nitinol, Dacron fabric, Polytetrafluoroethylene or PTFE, Silicone, or Polyurethane) or a biological material (for example, human or animal pericardium). The device 400 may be delivered percutaneously, through the chest (thoracoscopy), or using open heart surgical techniques. If delivered percutaneously, the device may be made from a super-elastic material (for example, Nitinol) enabling it to be folded and collapsed such that it can be delivered in a catheter, and will subsequently self-expand when released from the catheter. The

device may be secured to the mitral annulus with sutures or other attachment means (i.e. barbs, hooks, staples, etc).

Figure 5 shows a perspective view of an embodiment of the invention comprised of a bridge 540, spanning material 530, attachment means 550, and a base 520. In addition, the device is shown to have a framework 510. Preferably the framework 510 does not interfere with atrial contractions, instead contracting with the atrium. As such, the device 500 may have non-uniform flexibility to improve its function within the heart. The framework is shown here rising from the base 520 with two substantially parallel arched wires that connect to form a semicircular hoop above the base 520. The framework 510 helps to accurately position the device within the atrium, and also helps to secure the device within the atrium. The neo-leaflet comprised of the bridge 540 and spanning material 530 is shown in the closed valve position.

Figure 6 shows a perspective view of the embodiment of Figure 5 in the open valve position.

Figure 7 shows a perspective view of the embodiments shown in Figures 5 and 6 positioned within the left atrium of the heart.

Figures 8 and 9 show a perspective view of the embodiments of Figures 5 and 6 positioned within the left atrium of the heart. Figure 8 shows the embodiment in a closed valve position, and Figure 9 shows the embodiment in an open valve position. The sizing of the base 810 can vary depending upon the patient's needs.

Figure 10 shows a perspective view of an embodiment of the invention having a framework 1010 that avoids the pulmonary veins (not shown).

Figures 11 and 12 show a perspective view of a dual spring bridge neo-leaflet have an anterior bridge spanned by an anterior material 1110, and a posterior bridge spanned by a posterior material 1120. The framework 1130 shown here illustrates an alternative design. This embodiment also illustrates a base having clips 1140 that protrude below an imaginary plane formed by the annulus of the valve. Figure 11 shows the dual neo-leaflets in a closed valve position, and Figure 12 shows the dual neo-leaflets in an open valve position.

Figure 13 shows a perspective view of a damaged native anterior leaflet 1310 that is not connected to the chordae tendineae.

Figure 14 shows a perspective view of a device 1400 having a half sewing ring 1420 with a membrane 1410 that serves as a neo-annulus or a neo-leaflet. When serving as a neo-annulus, the membrane 1410 is a relatively immobile structure covering one of the native valve leaflets, particularly a damaged, missing or nonfunctional leaflet. The neo-annulus serves to extend the

native annulus and coapts with the remaining functional native leaflet to create a functioning mitral valve. When serving as a neo-leaflet, the membrane 1410 is a mobile structure that moves in response to blood flow, coapting with one of the native leaflets to create a functioning mitral valve. The neo-leaflet replaces the function of a damaged, missing or nonfunctional native leaflet. The device 1400 is attached to the mitral valve annulus via the half sewing ring 1420. This embodiment could be surgically attached to the valve annulus and/or combined with a framework for anchoring the device within the patient's atrium using catheter based intraluminal techniques.

Figure 15 shows a perspective view of a device 1500 having a full sewing ring 1530 with a membrane 1510 that serves as a neo-annulus or a neo-leaflet. The device 1500 has an opening 1520 though the sewing ring 1530 opposite the membrane 1510 for blood flow. Alternatively, this embodiment could have two neo-leaflets. This embodiment could be surgically attached to the valve annulus and/or combined with a framework for anchoring the device within the patient's atrium using catheter based intraluminal techniques.

Figure 16 shows a perspective view of a leaflet retainer 1600 that is positioned within the atrium on top of both native mitral valve leaflets. This embodiment is comprised of an outer ring 1610 and an inner ring 1630 connected by radial struts 1620. The interior region of the valve orifice remains unobstructed to blood flow with this embodiment. This embodiment could be surgically attached to the valve annulus and/or combined with a framework for anchoring the device within the patient's atrium using catheter based intraluminal techniques.

Figure 17 shows a perspective view of a leaflet retainer 1700 that is positioned within the atrium on top of both native mitral valve leaflets. This embodiment could be surgically attached to the valve annulus and/or combined with a framework for anchoring the device within the patient's atrium using catheter based intraluminal techniques.

Figure 18 shows a perspective view of a leaflet retainer 1800 that is positioned within the atrium on top of both native mitral valve leaflets. This embodiment could be surgically attached to the valve annulus and/or combined with a framework for anchoring the device within the patient's atrium using catheter based intraluminal techniques.

Figure 19 shows a perspective view of a leaflet retainer 1900 that is positioned on top of both native mitral valve leaflets. Alternatively, the leaflet retainers may be designed to retain only one leaflet, or a portion of a leaflet, depending on patient needs. The outer sections of this embodiment have anchors 1910 that distribute stresses along the atrial wall, helping to prevent erosion of the atrial walls. This embodiment could be surgically attached to the valve annulus

and/or combined with a framework for anchoring the device within the patient's atrium using catheter based intraluminal techniques.

Figure 20 shows a side view of the embodiment shown in Figure 19.

Figure 21 shows a perspective view of the embodiment shown in Figure 19.

Figure 22 through 26 show the sequence of steps for a catheter-based percutaneous deployment of an embodiment of the invention. This deployment technique applies to other embodiments as well. Initially, a guidewire is introduced into the vasculature via a peripheral venous access site, such as the femoral or jugular vein, or alternatively by means of surgical access through the right atrium. Figure 22 shows the introduction of a guidewire 2210 through the septum 2220 between the right and left atria. The guidewire is shown being introduced into the right atrium via the inferior vena cava 2230. Figure 23 shows a catheter 2320 being advanced over the guidewire 2310. Figure 24 shows an embodiment of the invention 2400 being released from the catheter after the guidewire has been removed. Alternatively, a guidewire could be used to place the device. Figure 25 shows an embodiment of the invention having an additional feature, a looped eyelet 2500 that is being placed within a pulmonary vein to help position the device within the atrial chamber. The looped eyelet 2500 could be advanced over a guidewire. Figure 26 shows an embodiment of the invention 2600 being positioned within the left atrium. The device 2600 can be positioned or repositioned within the atrium using a catheter deployed grasping instrument 2610.

Figure 27 shows a perspective view of an embodiment of the invention 2700 having a framework that partially fills the atrium.

Figure 28 shows a perspective view of an embodiment of the invention 2800 having dual neo-leaflets, 2830 and 2840. The device is comprised of a framework 2810 an annular base 2820, and the neo-leaflets, 2830 and 2840. The neo-leaflets supplement or replace native leaflets, and thus function as a one-way valve to allow blood to flow from the atrium to the ventricle, and to prevent blood from flowing from the ventricle to the atrium. This is accomplished because the neo-leaflets structure is similar to native leaflet structure.

Figure 29 shows a perspective view of an embodiment of the invention 2900 having a leaflet retainer 2910 positioned against a native leaflet as well as a framework structure 2920 that meanders about the atrium without interfering with the pulmonary veins. The leaflet retainer 2910 prevents the leaflet from prolapsing into the atrium due to the pressure differential during ventricular contractions, thus improving closure of the mitral valve and reducing regurgitation.

Figure 30 shows a perspective view of another embodiment of the invention 3000 consisting of a continuous wire or tube that forms a leaflet retainer and framework. The geometry of the framework is such that it spirals upward within the atrium. The device 3000 is secured in place because the framework expands within the atrium, and experiences mural pressures. The leaflet retainer is secured in place over a native leaflet by its coupling to the framework, and the leaflet retainer functions to prevent the native leaflet from experiencing prolapse. In addition, a coating that promotes tissue growth may aid in the fixation process of the framework within the atrium. However, the leaflet retainer section of the device 3000 may benefit from a coating that inhibits tissue growth, thus allowing the native leaflet to allow blood to flow into the ventricle.

Figure 31 shows a perspective view of a tulip shaped wire form configuration 3100 of the invention.

Figure 32 shows cutaway view of a tulip shaped wire form configuration 3200 of the invention. The illustration shows the device 3200 making contact with native leaflets, 3220 and 3210, to prevent prolapse. The device 3200 is comprised of a leaflet retainer section that functions to prevent the native leaflets, 3210 and 3220, from being blown into the atrium when the ventricle contracts. The leaflet retaining section is positioned directly over the native leaflets. In this embodiment, the leaflet retaining aspect of the device 3200 is shown to be integrally formed with the framework section of the device. However, in other embodiments, the leaflet retainer and framework may be separate structures which can be deployed separately for individual use or in combination.

Figure 33 shows a cutaway view of a tulip with a twist wire form configuration 3300 of the invention. The twist aspect enables the device to be shortened through twisting to decrease the longitudinal spring constant. The device 3300 is comprised of a leaflet retainer section that functions to prevent the native leaflets from being blown into the atrium when the ventricle contracts. The leaflet retaining section is positioned directly over the native leaflets. In this embodiment, the leaflet retaining aspect of the device 3300 is shown to be integrally formed with the framework section of the device. However, in other embodiments, the leaflet retainer and framework may be separate structures which can be deployed separately for individual use or in combination.

Figure 34 shows a cutaway view of the left atrium and left ventricle. The arrows on the left side of the figure indicate by way of example three different ways in which an embodiment of the invention, such as a leaflet retainer, neo-leaflet, or neo-annulus, may interact with the

mitral valve, or be positioned if replacing a leaflet. In other words, an embodiment of the invention may lie in a plane formed by the annulus of the mitral valve as indicated by the middle arrow 3410. Also, an embodiment of the invention may lie either above or below the plane of the annulus, as indicated by the top 3400 and bottom 3420 arrows, respectively. In addition, Figure 34 could also be used to illustrate potential movements when these components of the invention are configured as a spring bridge that spans the mitral annulus and actively moves with the valve leaflet(s). A spring bridge may be configured so that it is biased in the open valve position, and is forced shut by increasing pressure within the ventricle. Alternatively, the spring bridge may not be biased open or closed, but simply move in response to pressure differentials. Also, the spring bridge may be biased in the closed position.

Figure 35 shows a perspective view of mesh leaflet with buttressing 3500. The embodiment is comprised of a framework 3510 and leaflet retainer 3520. The interior region of the valve orifice 3530 of this embodiment is left open to facilitate the flow of blood between the heart's chambers. The leaflet retainer 3520 prevents native leaflets from being blown into the atrium upon ventricular contraction. The framework 3510 transmits mural pressures to the leaflet retainer, encouraging the leaflet retainer to remain positioned over the native leaflets.

Figure 36 shows a side view of a corona configuration 3600 of the invention. This embodiment may be used as a framework, to which a leaflet retainer or other valve enhancing device could be attached or coupled to.

Figure 37 shows a perspective view of a corona configuration 3700 of the invention *in situ* within a patient's left atrium.

Figure 38 shows a cutaway view of a heart, having both native leaflets, 3810 and 3820, intact.

Figure 39 shows a cutaway view of a heart with one embodiment of the invention 3900.

Figure 40 shows a cutaway view of a heart with one intact mitral valve leaflet 4010, and one mitral valve leaflet excised, or missing. The chords 4020 of the removed leaflet are shown disconnected.

Figure 41 shows a cutaway view of a heart with one embodiment of the invention 4100. In addition, the shown embodiment has one neo-leaflet 4110. This neo-leaflet 4110 may be rigid, semi-rigid, or flexible.

Figure 42 shows a cutaway view of a heart with both mitral valve leaflets removed. The chords 4210 are shown disconnected.

Figure 43 shows a cutaway view of a heart with one embodiment of the invention 4300 having two neo-leaflets.

These devices may be delivered to the heart via open heart surgery, through the chest, or through a remote blood vessel. Examples of delivery through a remote blood vessel include the use of guidewires and catheters. They can be advanced into the right atrium through the superior or inferior vena cava (transluminally, via a peripheral venous insertion site, such as the femoral or jugular vein), or into the left ventricle through the aorta. The left atrium can be accessed from the right atrium through the septum. Alternatively, the left atrium can be accessed from the left ventricle through the mitral valve using a transluminal procedure gaining access via a peripheral arterial insertion site, such as the femoral artery. Echo techniques are used to determine whether a patient is experiencing regurgitation, and various imaging techniques can be used to position the device.

The devices shown may be anchored within the left atrium using barbs, staples, adhesives, magnets, etc. In addition, the devices may be coated with various materials to either promote (Dacron) or inhibit (heparin) tissue growth around the devices, to prevent thrombosis, or coated with other desired materials to encourage other desirable characteristics. Anchoring can also be done on the opposite (ventricular) side of the valve.

While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention it will become apparent to one of ordinary skill in the art that many modifications, improvements and sub combinations of the various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof.

We claim:

1. A medical device comprising:

a base member having a shape such that it tracks the circumference of a native heart valve annulus;

and a bridge member extending from the base member over the heart valve orifice, and supported by the base member.

2. The medical device of claim 1, further comprising a spanning material, the spanning material suspended from the bridge member, and adjacent portions of the base member, wherein the spanning material is coupled to the bridge member and adjacent portions of the base member by an attachment means.

3. The medical device of claim 1, wherein the bridge member is manufactured from a super-elastic material.

4. The medical device of claim 1, wherein the base member is sized to change the shape of the native valve annulus when attached to the native valve annulus.

5. The medical device of claim 1, wherein the spanning material is from a group consisting of Nitinol, Dacron fabric, Polytetrafluoroethylene, Silicone, Polyurethane, human pericardium, and animal pericardium.

6. The medical device of claim 1, wherein the attachment means is selected from a group consisting of sewing, gluing, welding, and wrapping the spanning material around itself.

7. The medical device of claim 1, further comprising a framework coupled to the base member and rising from the base member and into the surrounding heart chamber, the reactive forces of the heart on the framework transmitted through the framework and into the annulus retainer.

8. The medical device of claim 7, wherein the framework is shaped to avoid the pulmonary veins.

9. A medical device comprising:

a base member shaped such that it tracks the circumference of a native heart valve annulus,

a set of bridge members extending from the base member over the heart valve orifice, and supported by the base member,

and a spanning material suspended from each bridge member, and adjacent portions of the base member,

wherein the spanning material is coupled to the bridge member and adjacent portions of the base member by an attachment means.

10. The medical device of claim 9, wherein the bridge members are manufactured from a super-elastic material.

11. The medical device of claim 9, wherein the base member is sized to change the shape of the native valve annulus when attached to the native valve annulus.

12. The medical device of claim 9, wherein the spanning material is from a group consisting of Nitinol, Dacron fabric, Polytetrafluoroethylene, Silicone, Polyurethane, human pericardium, and animal pericardium.

13. The medical device of claim 9, wherein the attachment means is selected from a group consisting of sewing, gluing, welding, and wrapping the spanning material around itself.

14. The medical device of claim 9, further comprising a framework coupled to the base member and rising from the base member and into the surrounding heart chamber, the reactive forces of the heart on the framework transmitted through the framework and into the annulus retainer.

15. The medical device of claim 14, wherein the framework is shaped to avoid the pulmonary veins.

16. The medical device of claim 9, further including clips, the clips protrude from the base member and press into the ventricular side of the annulus.

17. A medical device comprising:
a semicircular annular ring,
and a spanning material,
wherein the spanning material is coupled to the semicircular annular ring.

18. The medical device of claim 17, wherein the semicircular annular ring is manufactured from a super-elastic material.

19. The medical device of claim 17, wherein the semicircular annular ring is sized to change the shape of the native valve annulus when attached to the native valve annulus.

20. The medical device of claim 17, wherein the spanning material is from a group consisting of Nitinol, Dacron fabric, Polytetrafluoroethylene, Silicone, Polyurethane, human pericardium, and animal pericardium.

21. A medical device comprising:
a circular annular ring,
and a spanning material,
wherein the spanning material is coupled to the circular annular ring such that the spanning material spans a portion of the circular annular ring to function as a coaptation surface for an functioning native leaflet.

22. The medical device of claim 21, wherein the circular annular ring is manufactured from a super-elastic material.

23. The medical device of claim 21, wherein the circular annular ring is sized to change the shape of the native valve annulus when attached to the native valve annulus.

24. The medical device of claim 21, wherein the spanning material is from a group consisting of Nitinol, Dacron fabric, Polytetrafluoroethylene, Silicone, Polyurethane, human pericardium, and animal pericardium.

25. A medical device comprising:

an outer hoop,

an inner hoop,

and struts that radiate between the inner and outer hoops,

wherein the struts are coupled to the outer and inner hoops.

26. The medical device of claim 25, wherein the medical device is manufactured from a super-elastic material.

27. The medical device of claim 25, wherein the medical device is sized to change the shape of the native valve annulus when attached to the native valve annulus.

28. A medical device, comprising:

a wire shaped to encircle the annulus of a heart valve, and radiate along the plane of the annulus both toward and away from the center of the valve orifice in a rhythmic pattern that enables the wire to contact both the valve leaflets and the adjacent heart walls.

29. The medical device of claim 28, wherein the wire is manufactured from a super-elastic material.

30. The medical device of claim 28, wherein the wire may be deployed from an intravascular catheter device.

31. A medical device, comprising:

a wire shaped to encircle the annulus of a heart valve, and radiate along the plane of the annulus both toward and away from the center of the valve orifice in a rhythmic pattern that enables the wire to contact both the valve leaflets and the adjacent heart walls, the wire contacting the heart walls forming a anchoring member that provides a holding force to the retainer by embedding into adjacent tissue without damaging it.

32. The medical device of claim 31, wherein the wire is manufactured from a super-elastic material.

33. A medical device, comprising:

a heart chamber framework having two hoops positioned in approximately parallel planes and connected by vertical struts that are coupled to each hoop.

34. The medical device of claim 33, wherein the medical device is manufactured from a super-elastic material.

35. A medical device comprising:

a heart chamber framework having a first hoop and a second hoop, the hoops positioned in parallel planes and connected by vertical struts that are coupled to each hoop,

and a neo-leaflet coupled to the first hoop, positioned to supplement or replace a native leaflet.

36. The medical device of claim 35, wherein the framework is manufactured from a super-elastic material.

37. The medical device of claim 35, further comprising a second neo-leaflet coupled to the interior surface of the first hoop, positioned to supplement or replace a native leaflet.

38. A medical device comprising:

a leaflet retainer, the leaflet retainer formed of a wire that is shaped to extend over a leaflet and restrict the leaflet's movements upstream of blood flow,

and a framework, the framework formed of a wire that is shaped to extend into the upstream heart chamber, and to contact the upstream chamber and transmit force from the chamber to the framework and then to the leaflet retainer,

wherein the leaflet retainer and framework are comprised of a continuous wire.

39. The medical device of claim 38, wherein the medical device is manufactured from a super-elastic material.

40. The medical device of claim 38, wherein the device may be deployed from an intravascular catheter device.

41. A medical device comprising:

a tulip-shaped wire form, wherein the tulip-shaped wire form has a framework and leaflet retainer, the leaflet retainer formed of a wire that is shaped to extend over one or more leaflets and restrict the leaflets movements upstream of blood flow,

and a framework, the framework formed of a wire that is shaped to extend into the upstream heart chamber, and to contact the upstream chamber and transmit force from the chamber to the framework and then to the leaflet retainer,

wherein the leaflet retainer and framework are comprised of a continuous wire.

42. The medical device of claim 41, wherein the wire form is manufactured from a super-elastic material.

43. A medical device comprising:

a twisted tulip-shaped wire form, wherein the twisted tulip-shaped wire form has a framework and leaflet retainer, the leaflet retainer formed of a wire that is shaped to extend over one or more leaflets and restrict the leaflets movements upstream of normal blood flow,

and a framework, the framework formed of a wire that is shaped to extend into the upstream heart chamber, and to contact the upstream chamber and transmit force from the chamber to the framework and then to the leaflet retainer,

wherein the leaflet retainer and framework are comprised of a continuous wire.

44. The medical device of claim 43, wherein the wire form is manufactured from a super-elastic material.

45. A medical device comprising:

a mesh-shaped wire form, wherein the mesh-shaped wire form has a framework and leaflet retainer, the leaflet retainer formed of a wire that is shaped to extend over one or more leaflets and restrict the leaflets movements upstream of normal blood flow,

and a framework, the framework formed of a wire that is shaped to extend into the upstream heart chamber, and to contact the upstream chamber and transmit force from the chamber to the framework and then to the leaflet retainer,

wherein the leaflet retainer and framework are comprised of a continuous wire.

46. The medical device of claim 45, wherein the medical device is manufactured from a super-elastic material.

47. A medical device, comprising:

a corona-shaped wire form, wherein the corona-shaped wire form is formed of a single wire that radiates between the valve base and the chamber apex and contacts the adjacent chamber walls.

48. The medical device of claim 47, wherein the medical device is manufactured from a super-elastic material.

49. A method for installing medical devices:

introducing a guidewire into a patient's blood vessel;

advancing the guidewire into the heart;

advancing a catheter over the guidewire, the catheter pre-loaded with a medical device comprising:

a base member, the base member having a shape that tracks the circumference of a native heart valve annulus; and

a bridge member, the bridge member extending from the base member over the heart valve orifice, and supported by the base member;

advancing the catheter within the vessel so that the medical device reaches its desired position within the heart;

releasing the medical device into the desired location within the heart;

positioning the medical device within the desired location of the heart;

and withdrawing the catheter from the patient.

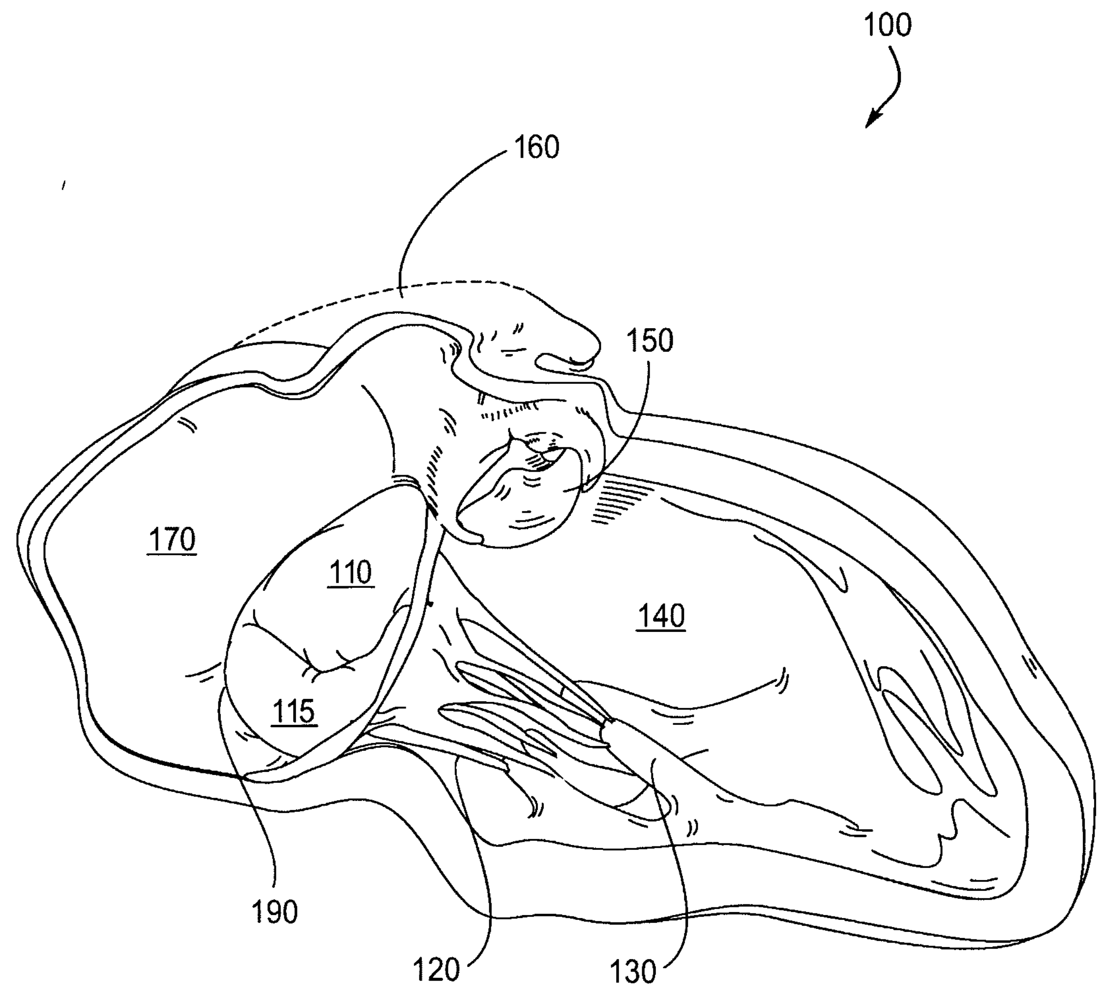


FIG 1

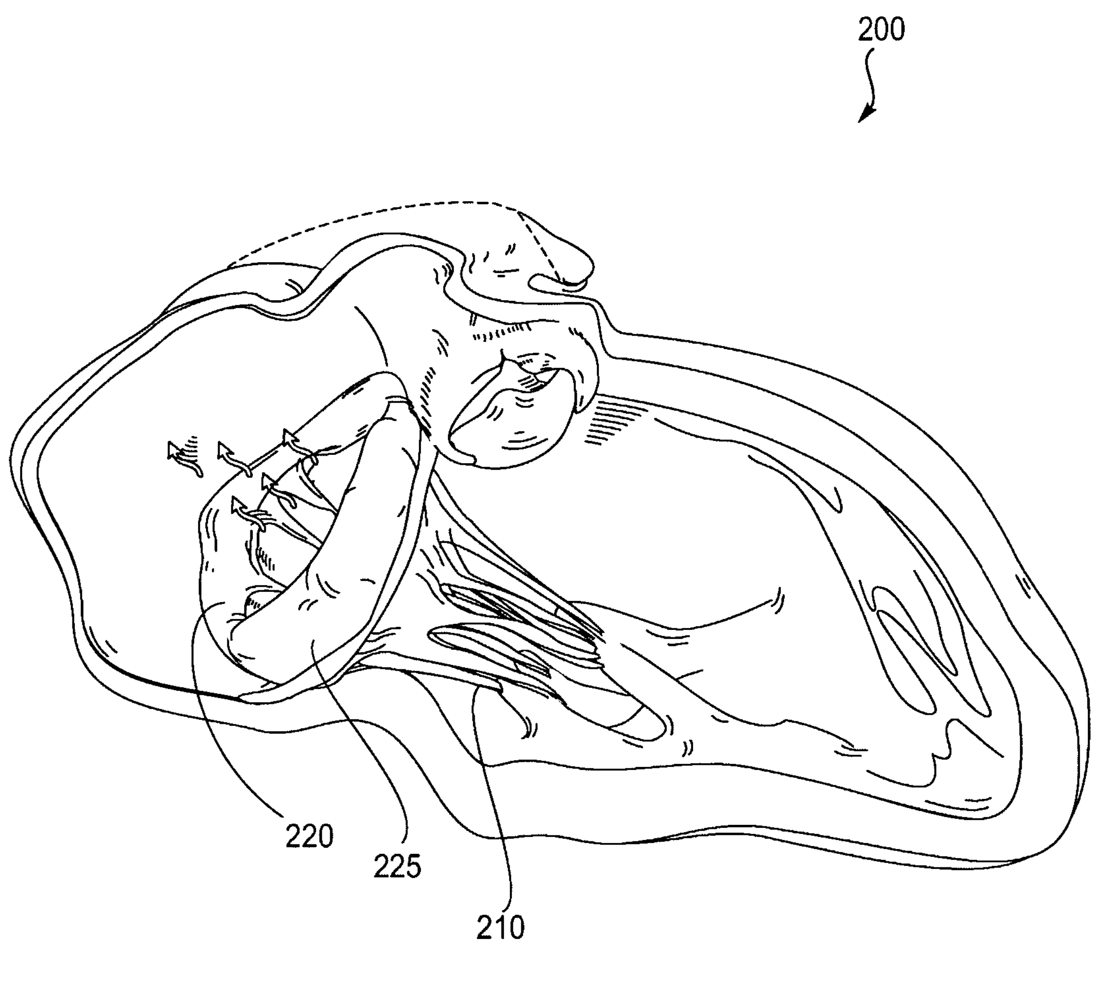
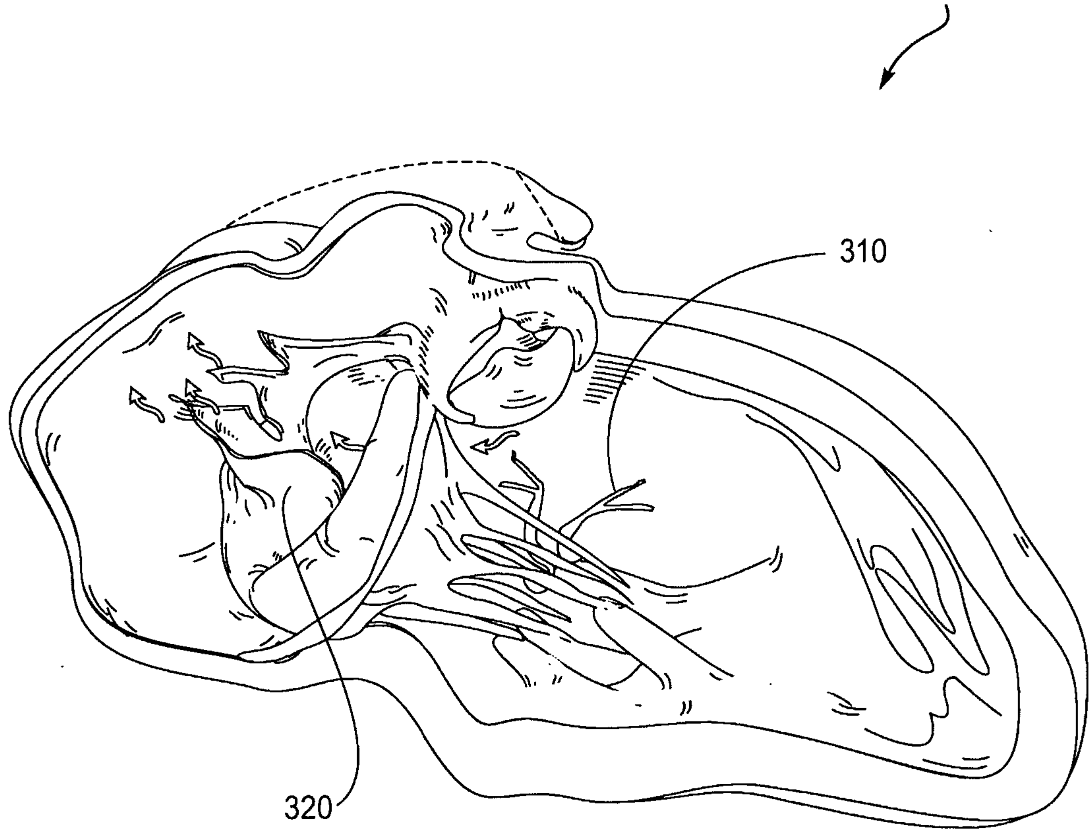


FIG 2



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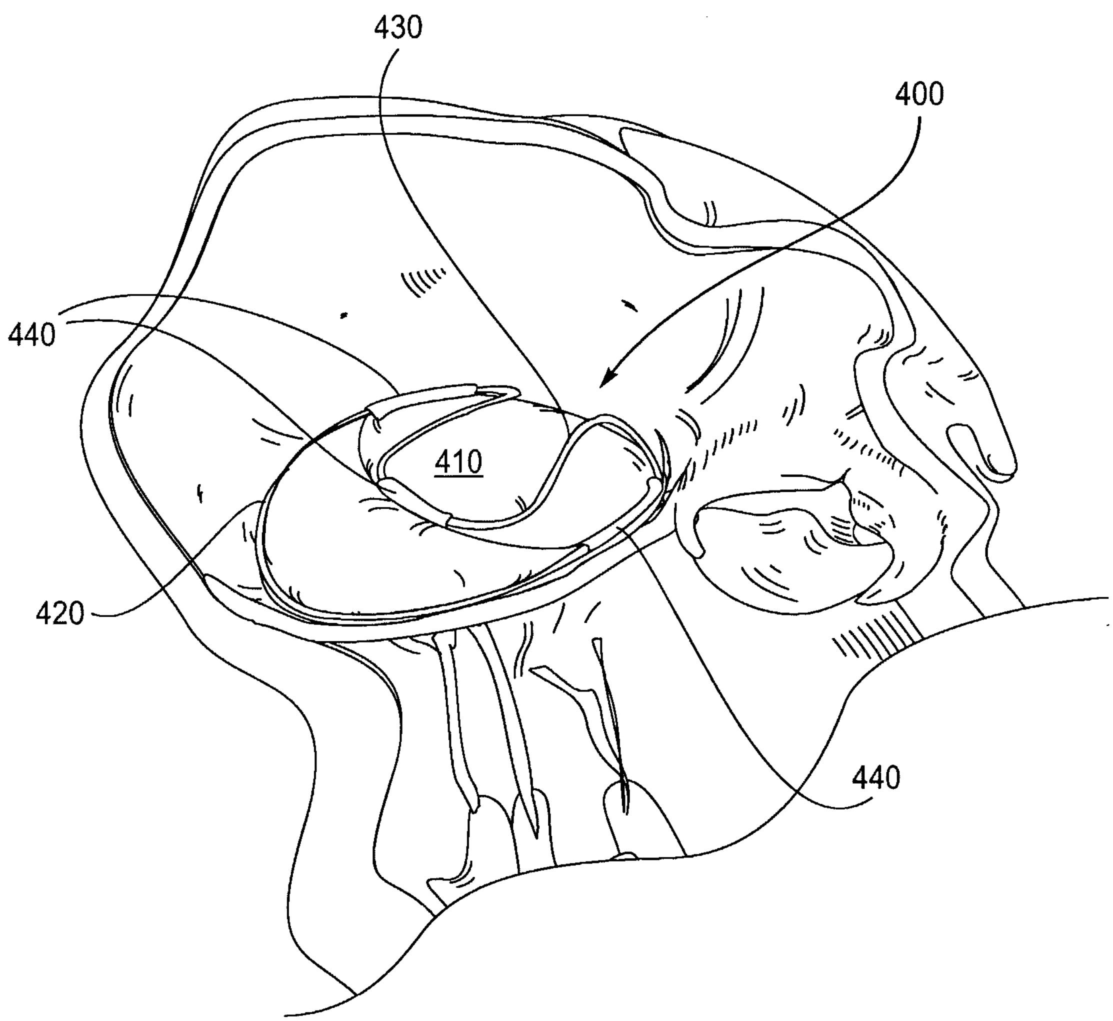

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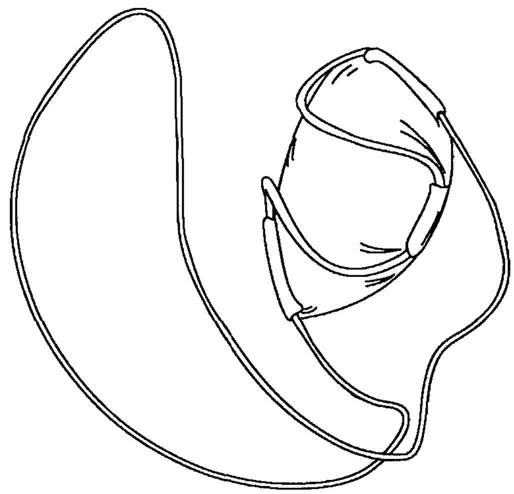

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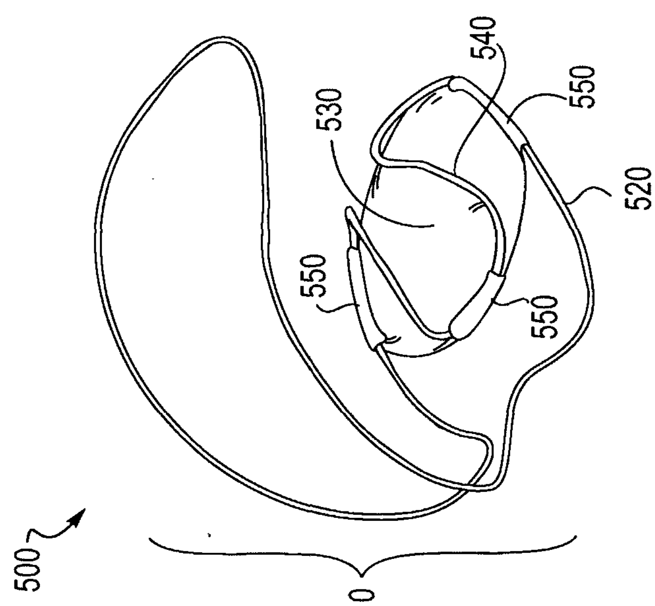
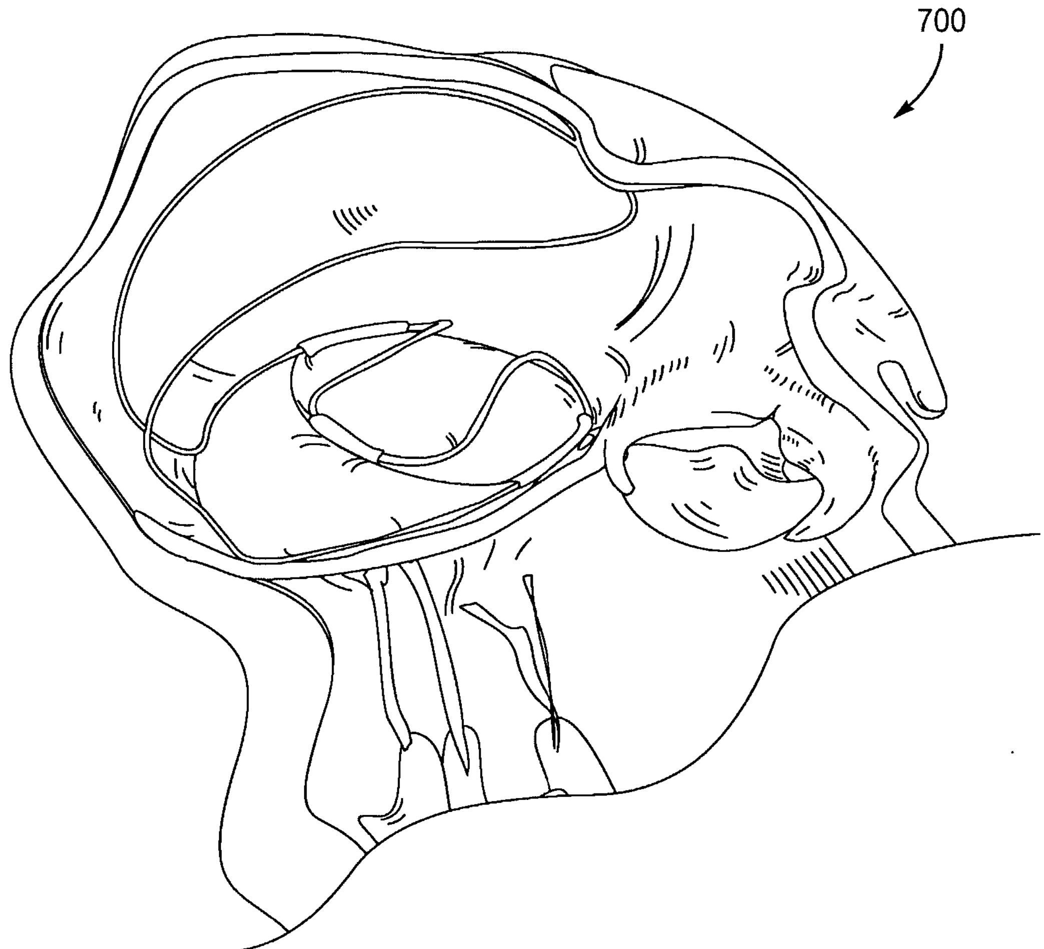


FIG 5



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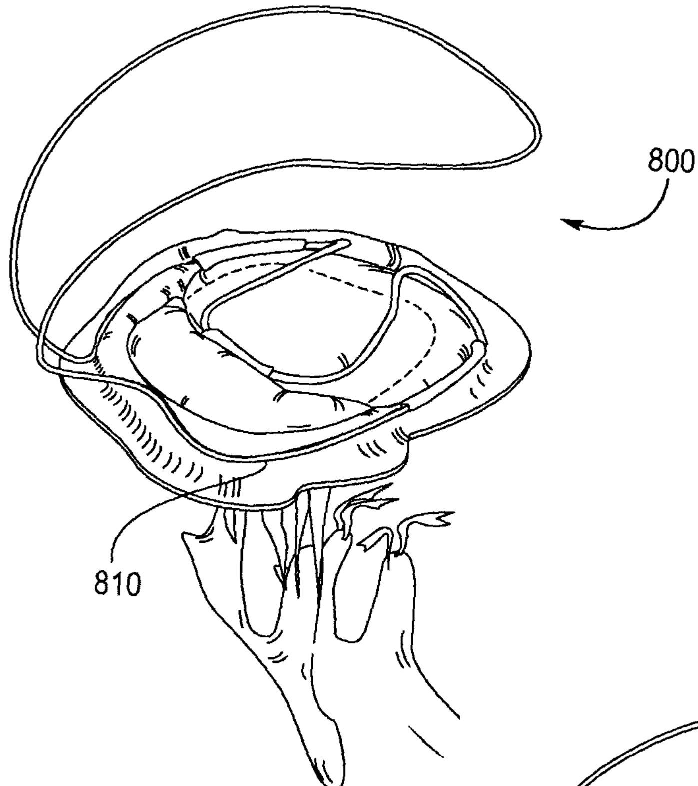

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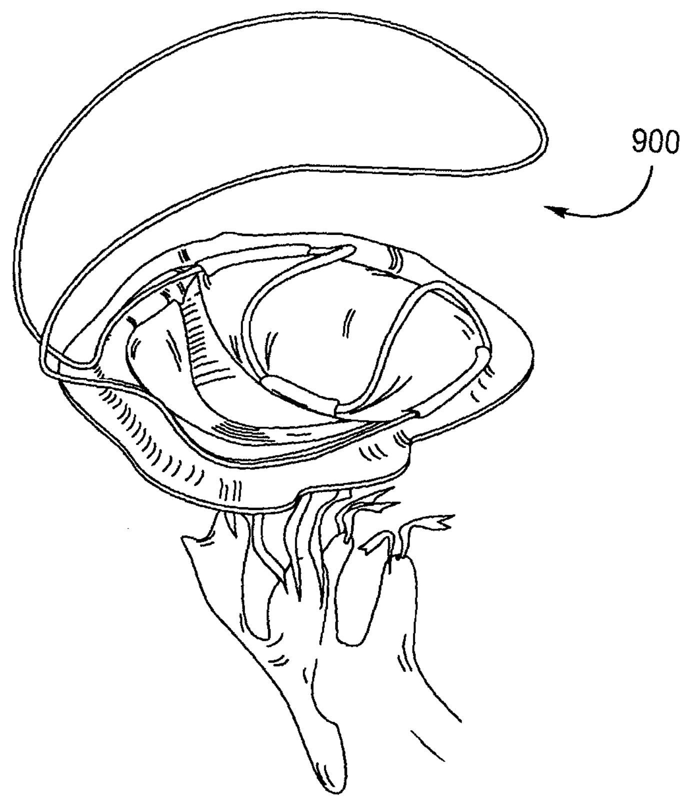


FIG 9

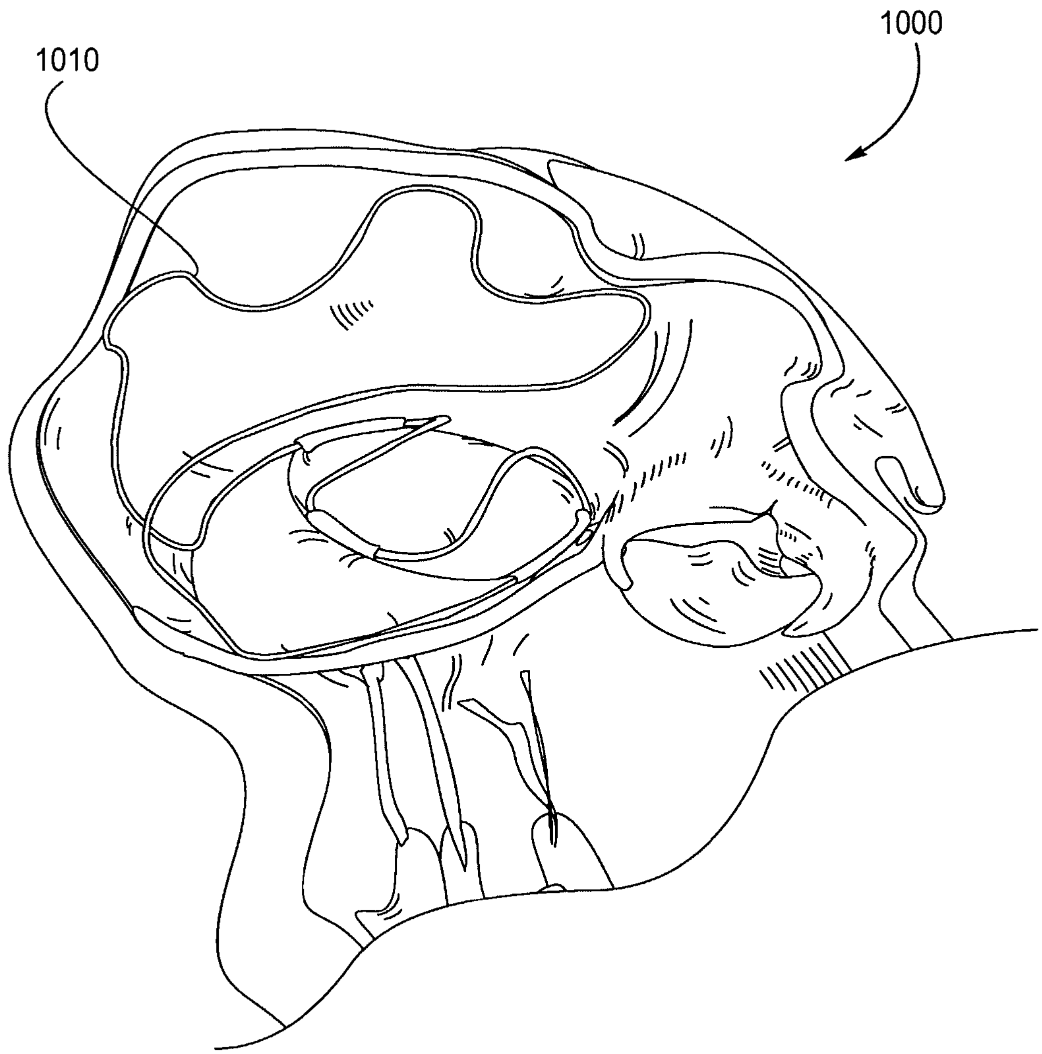
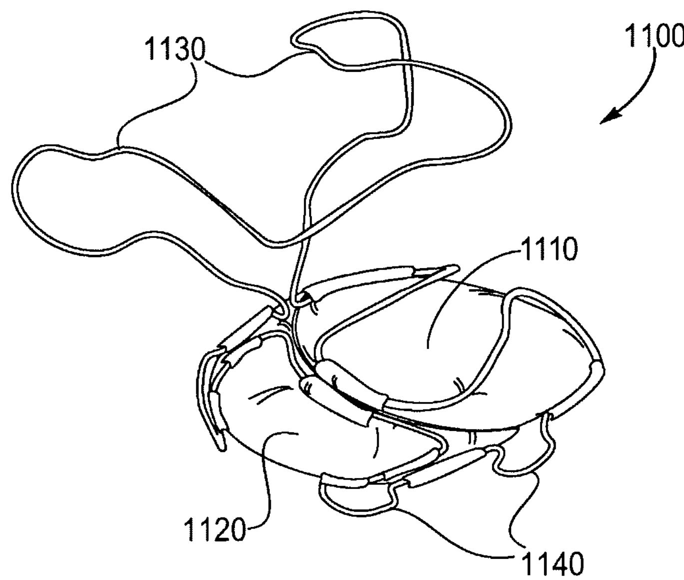


FIG 10



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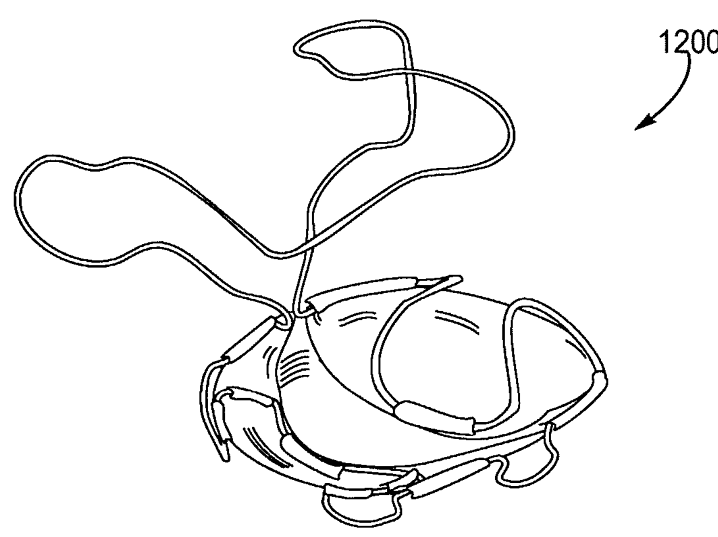

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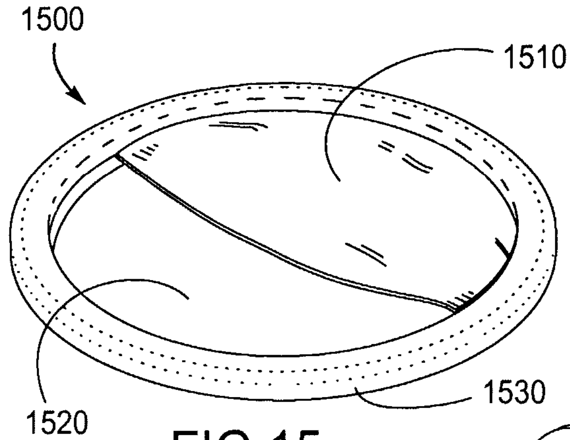

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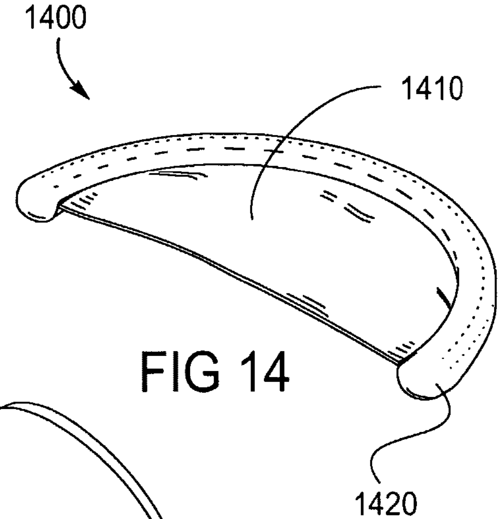


FIG 14

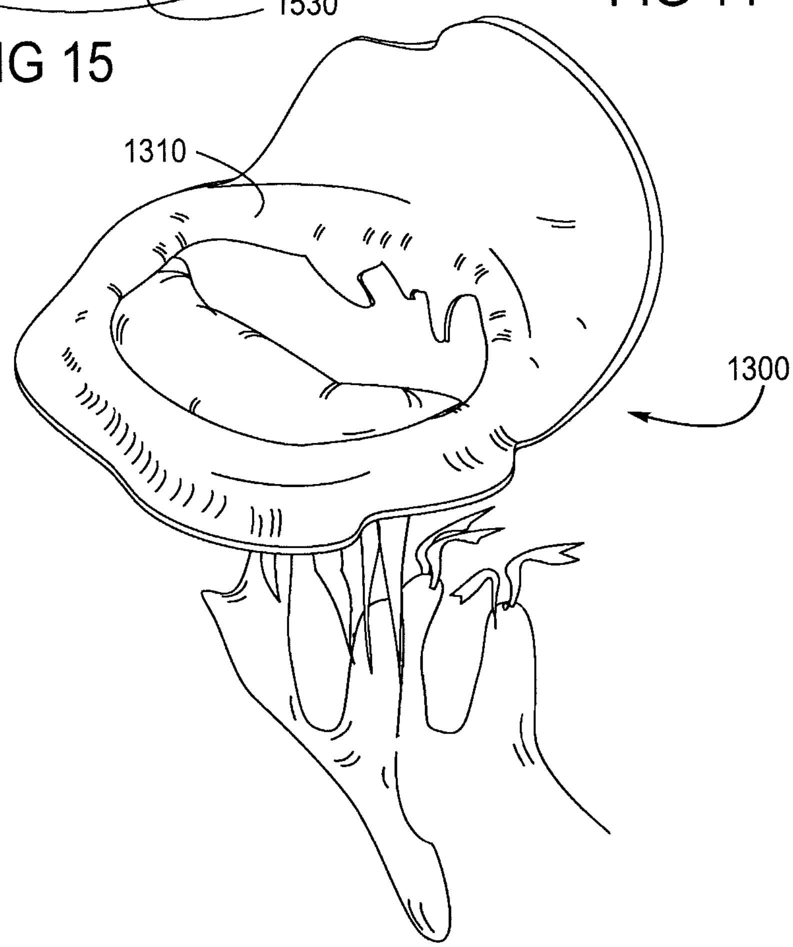
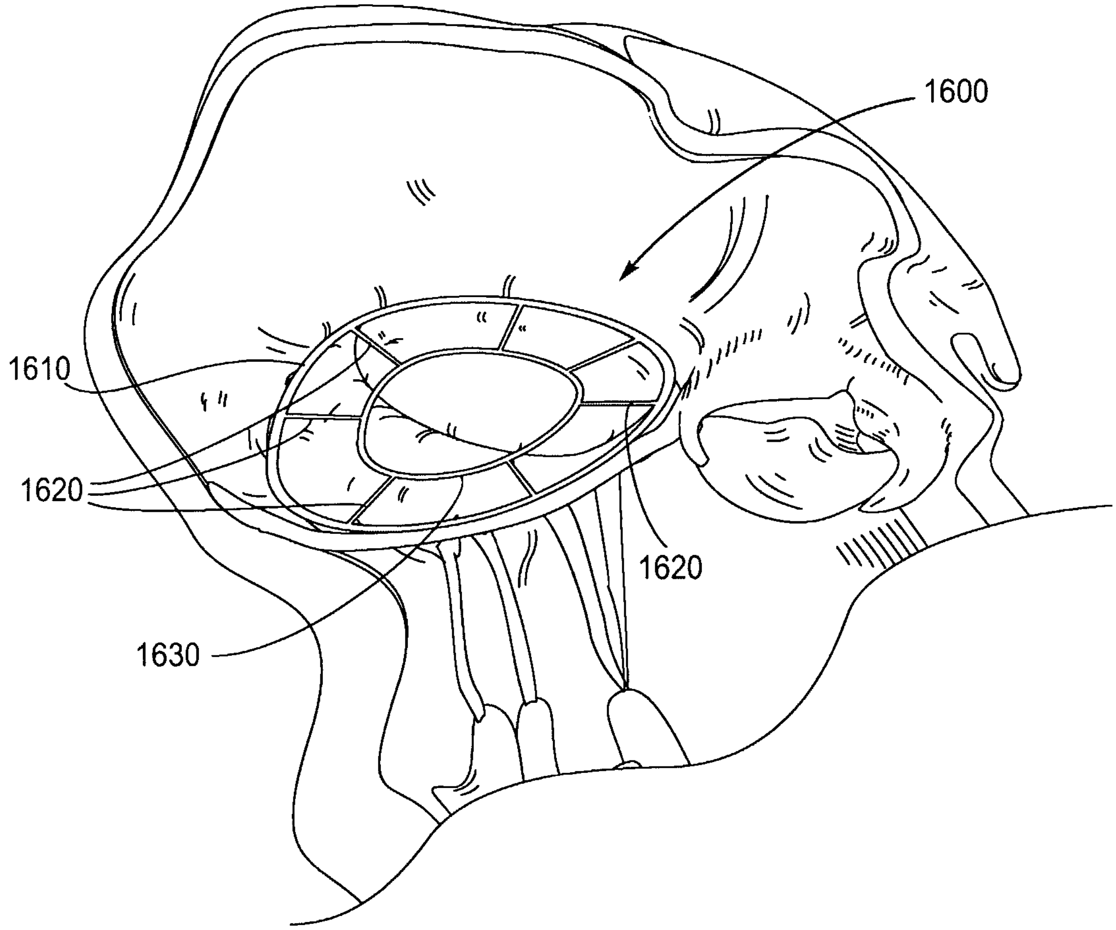


FIG 13



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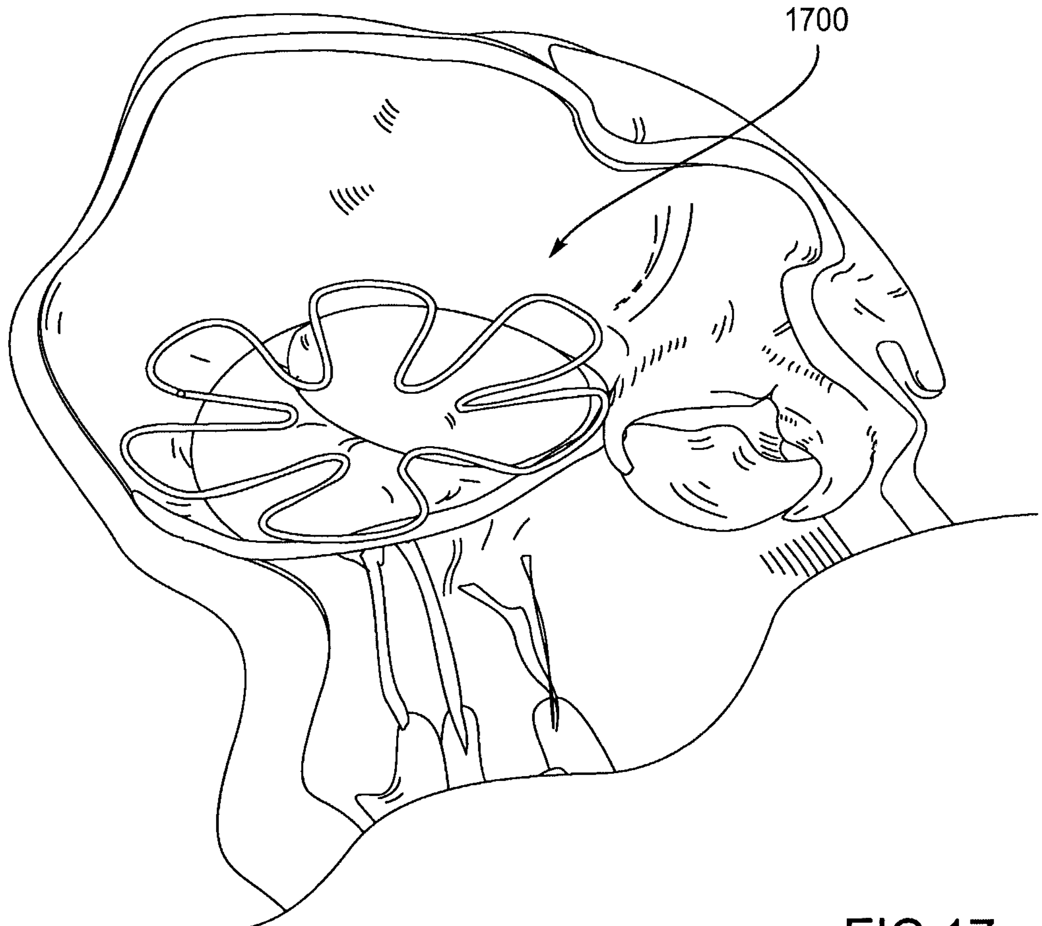

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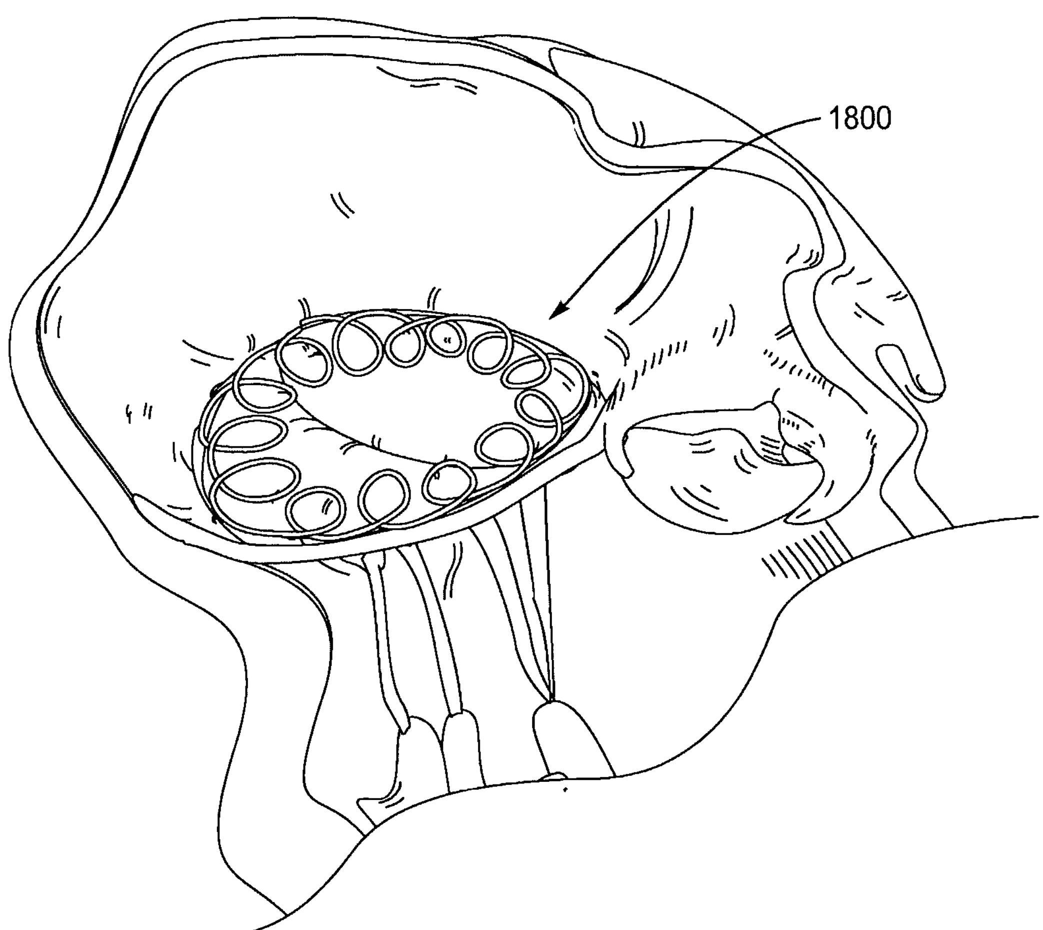

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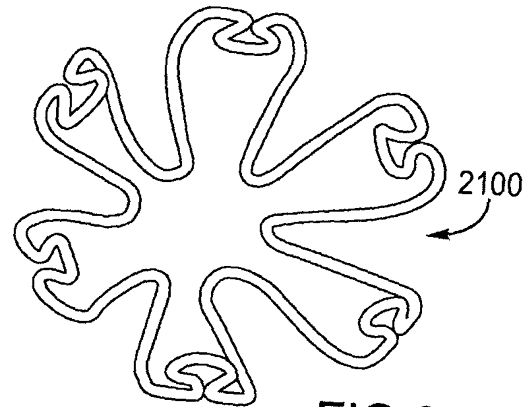

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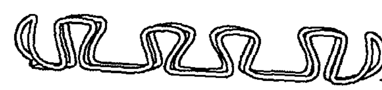

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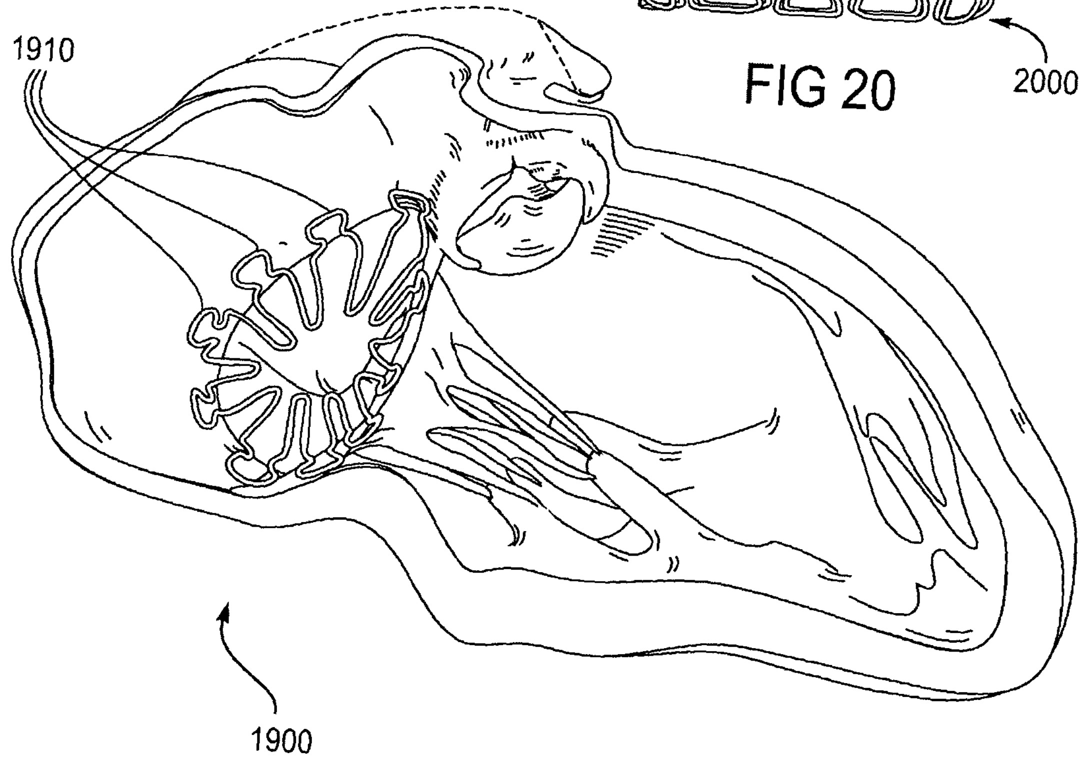

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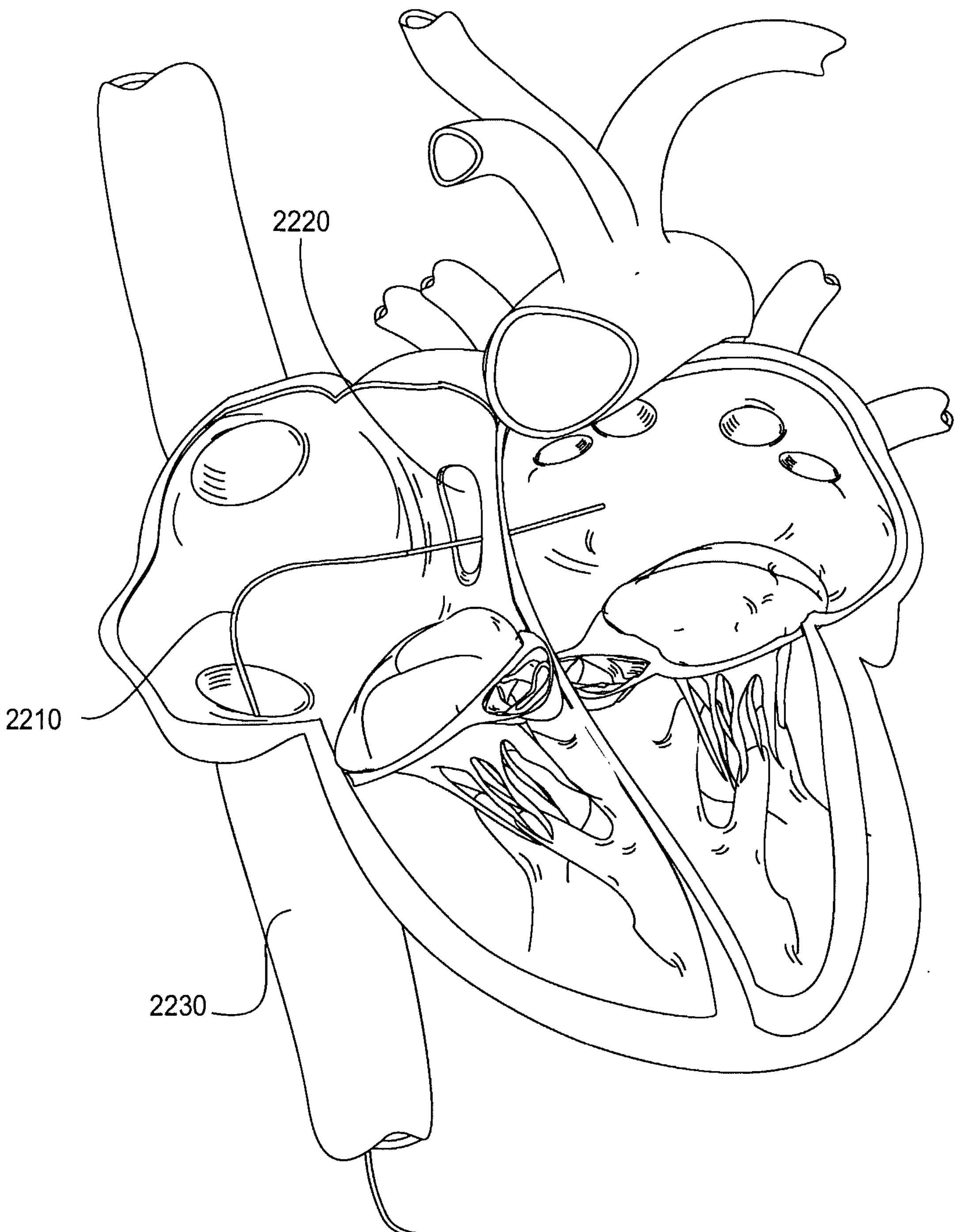
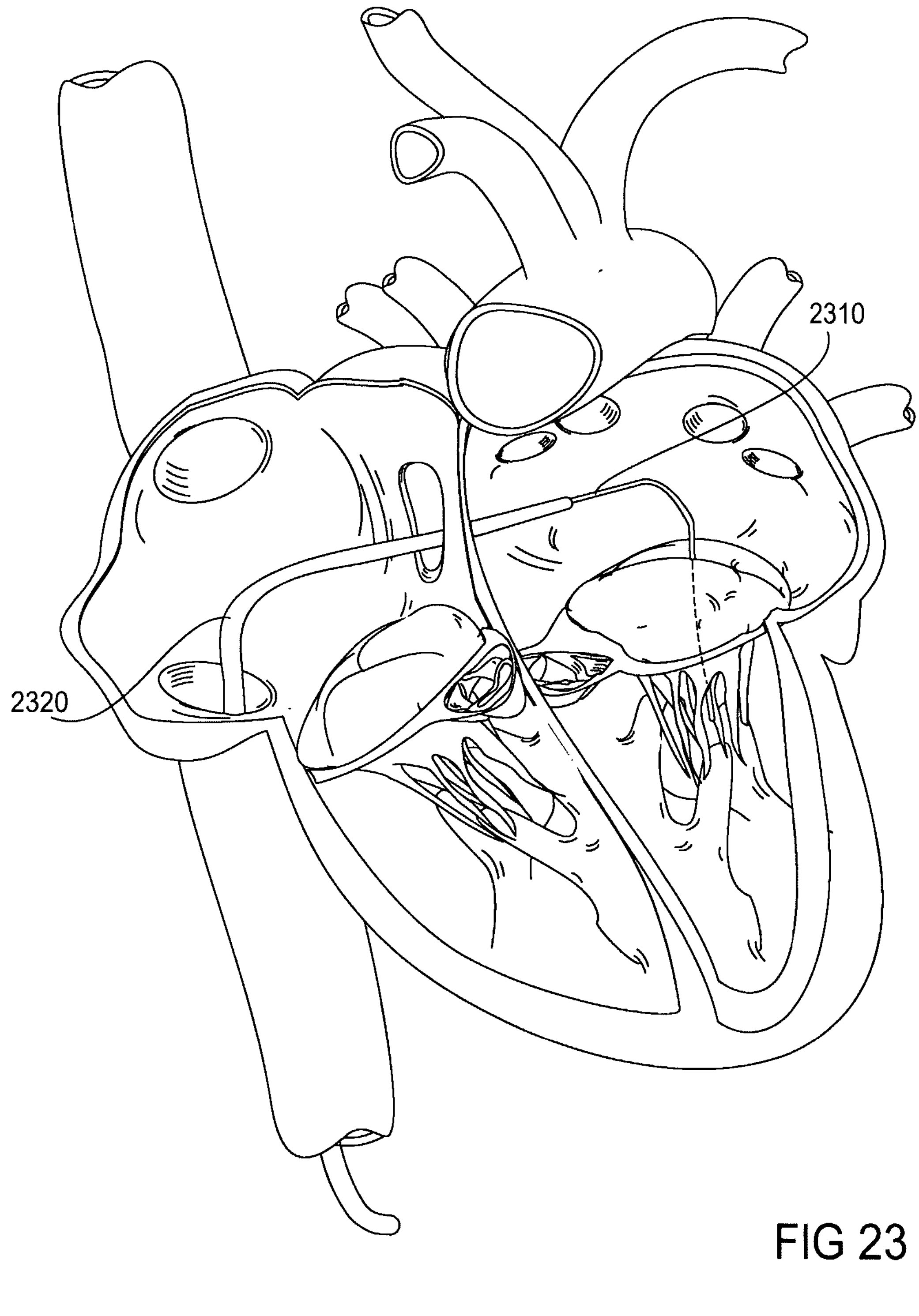


FIG 22



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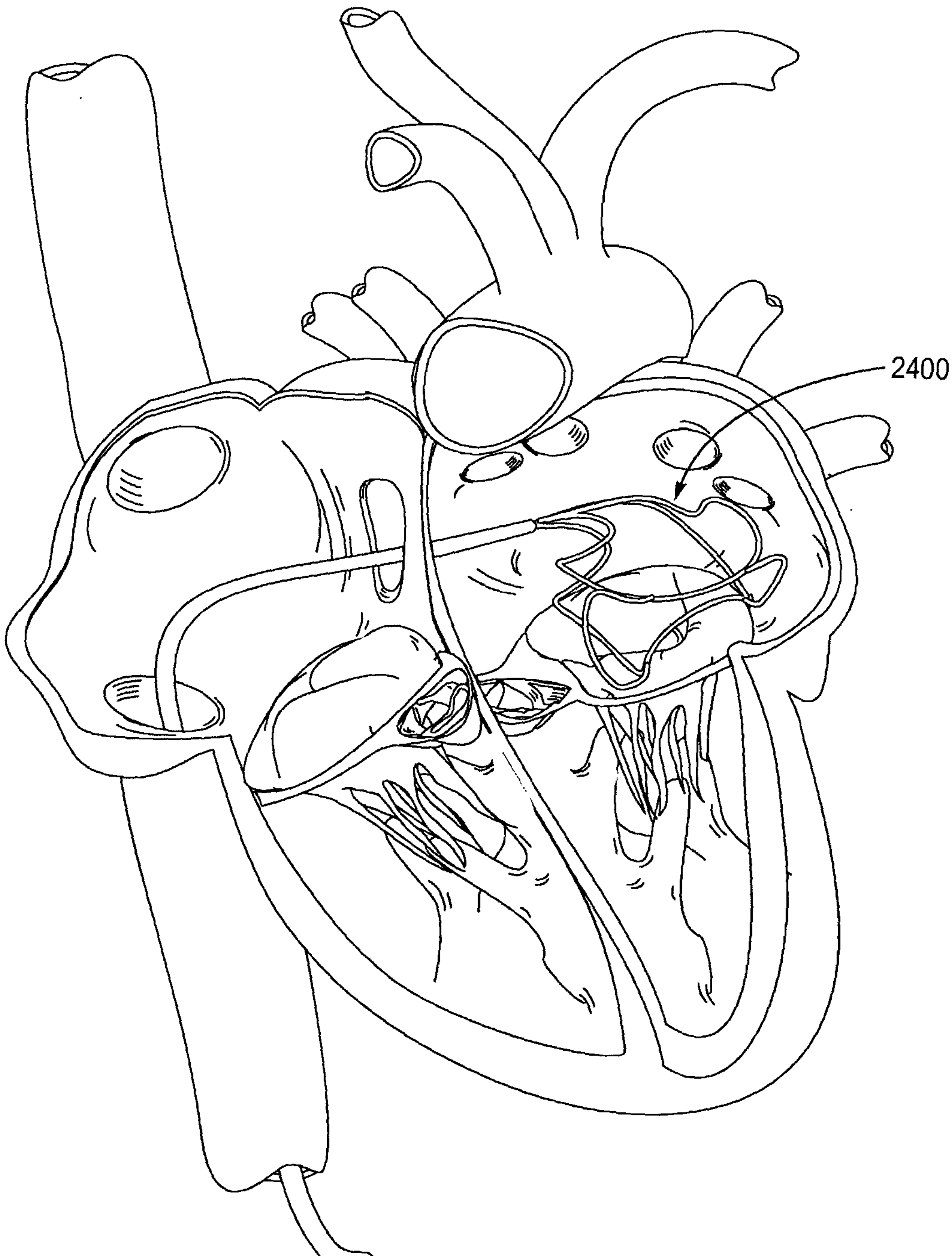


FIG 24

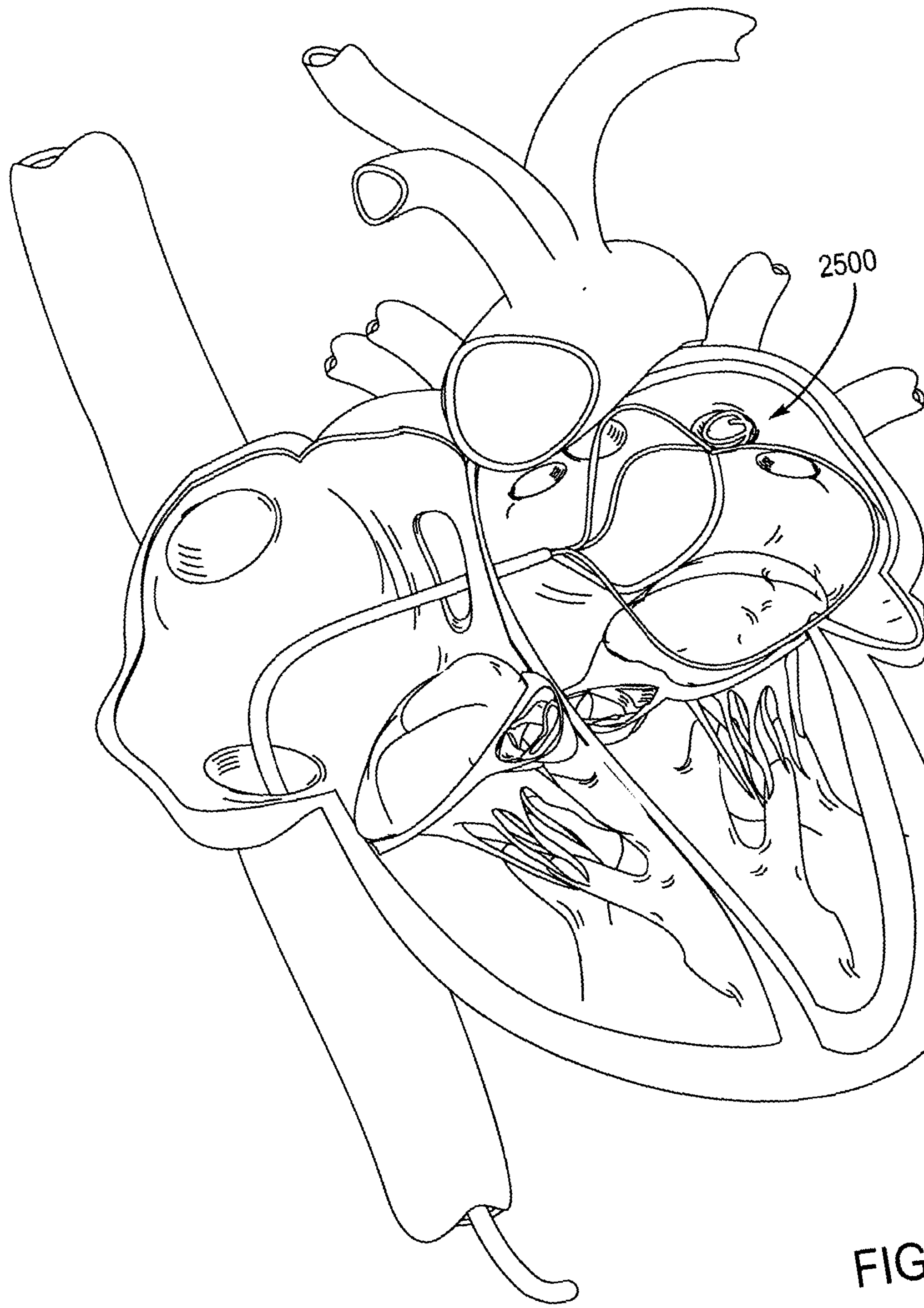


FIG 25

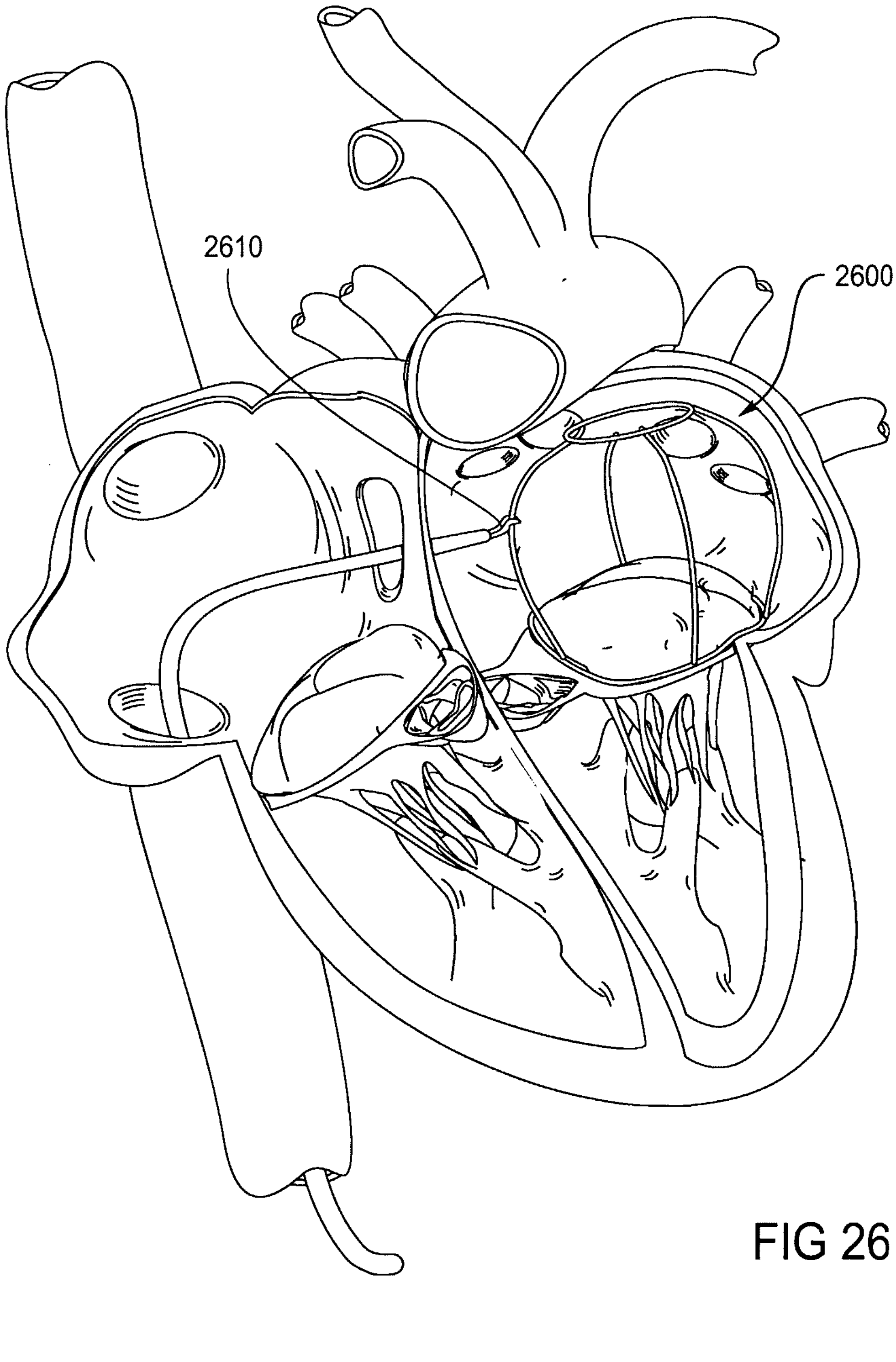
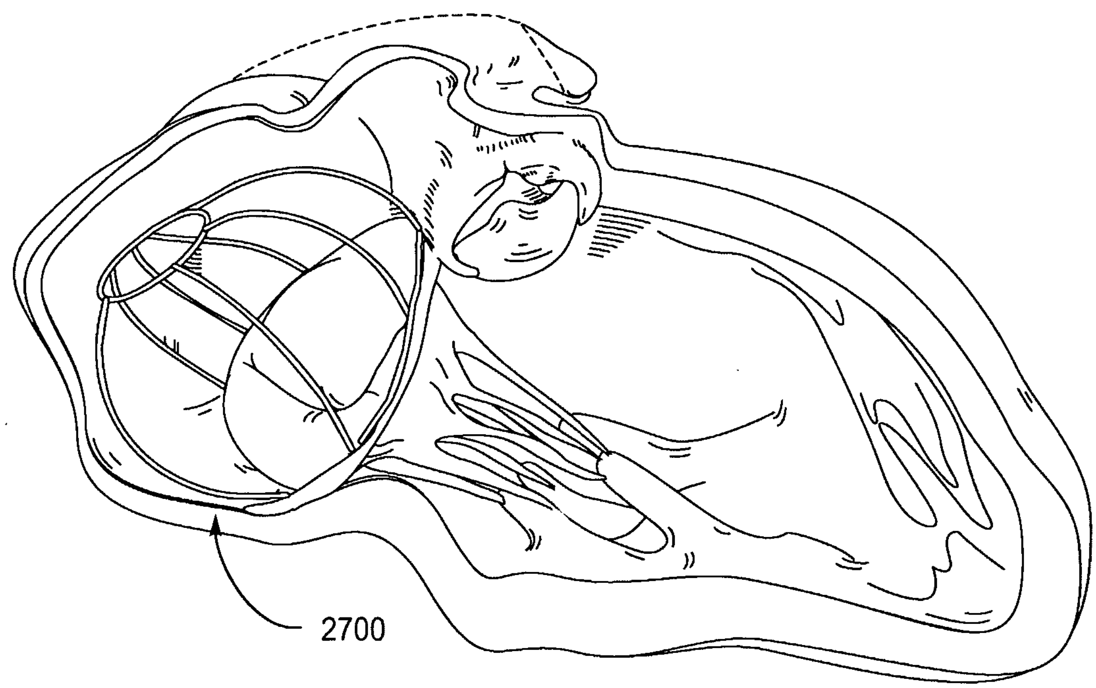


FIG 26



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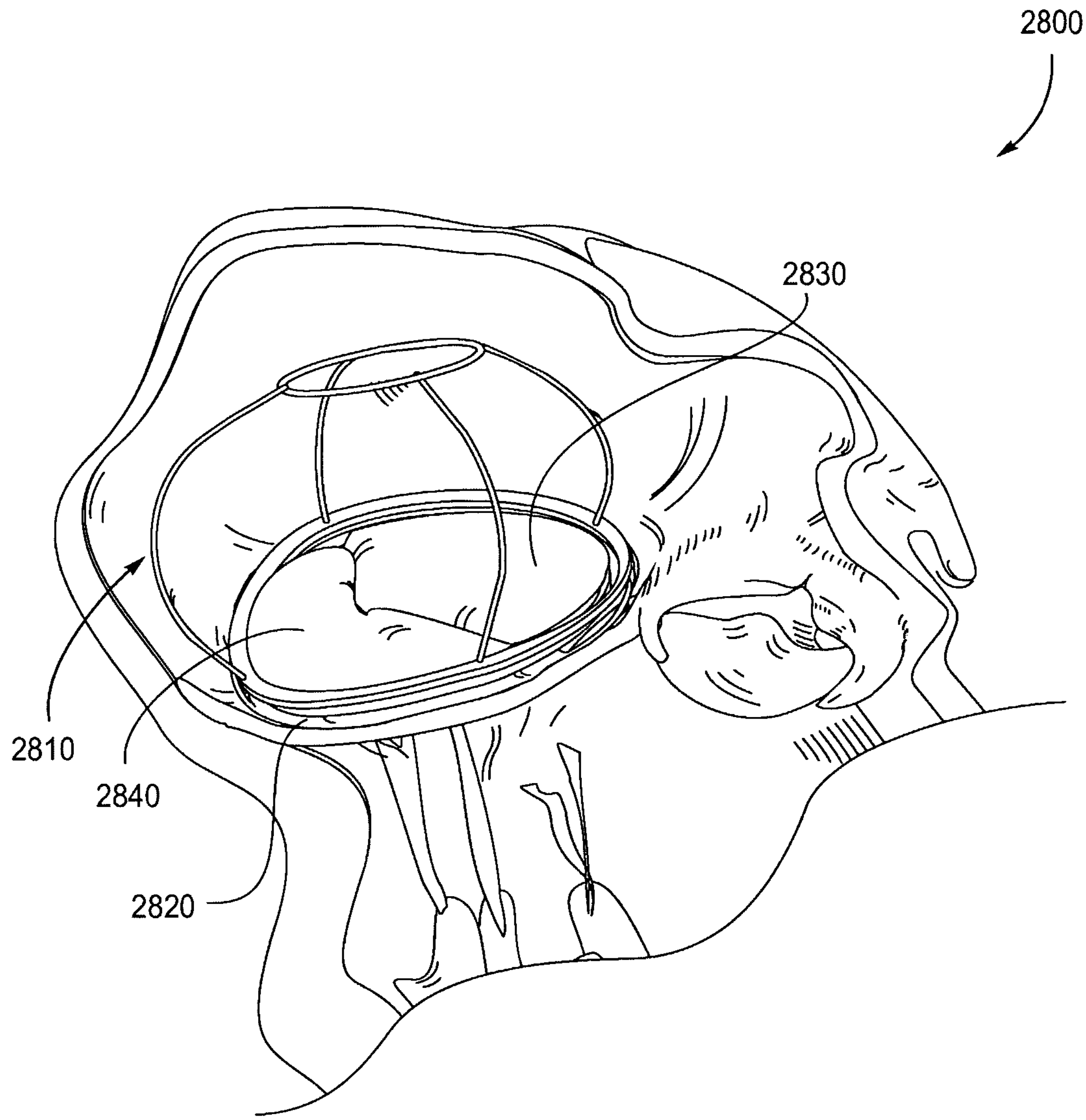
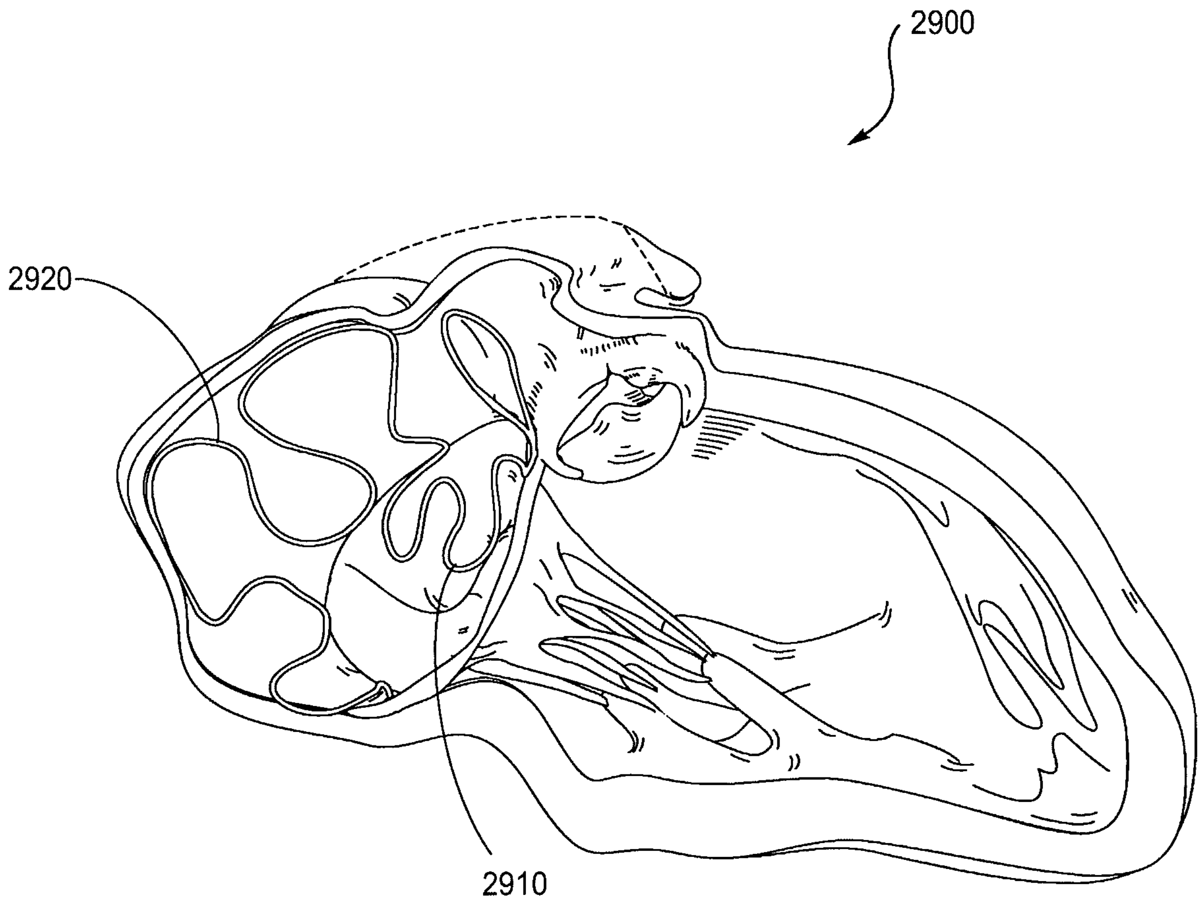


FIG 28



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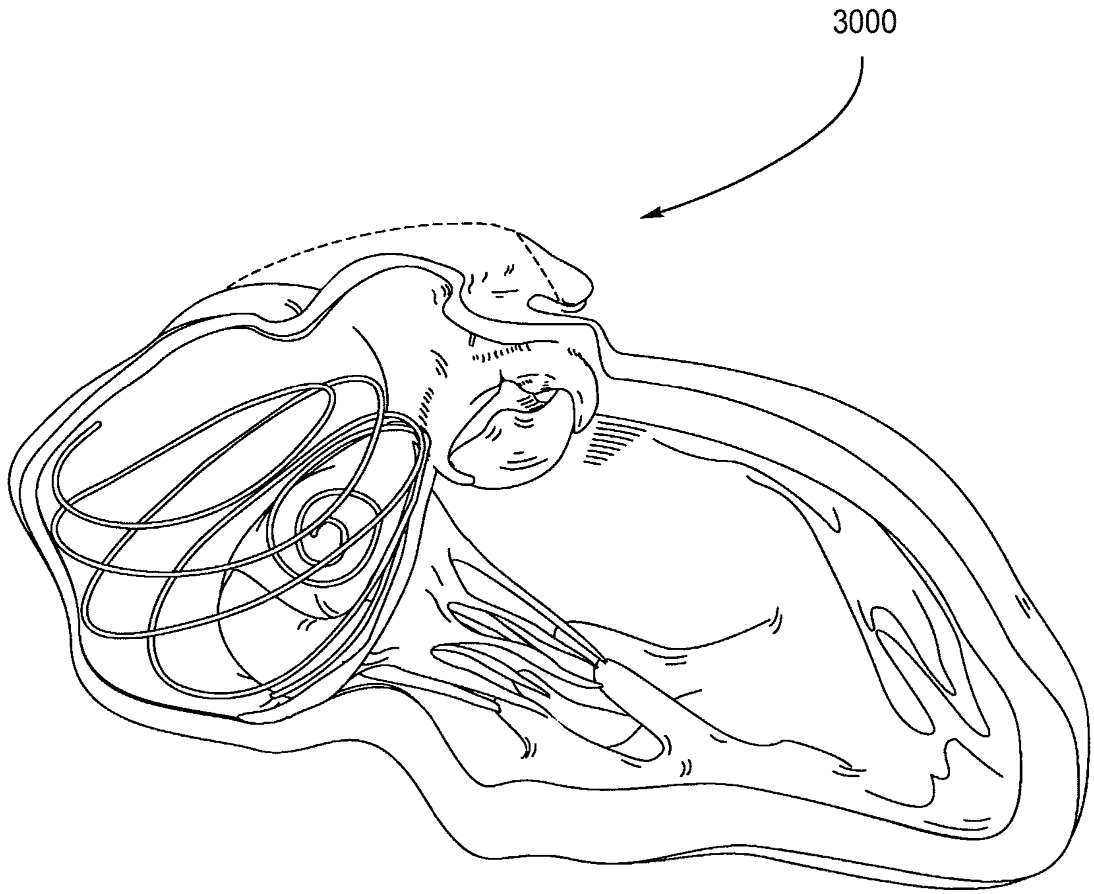


FIG 30

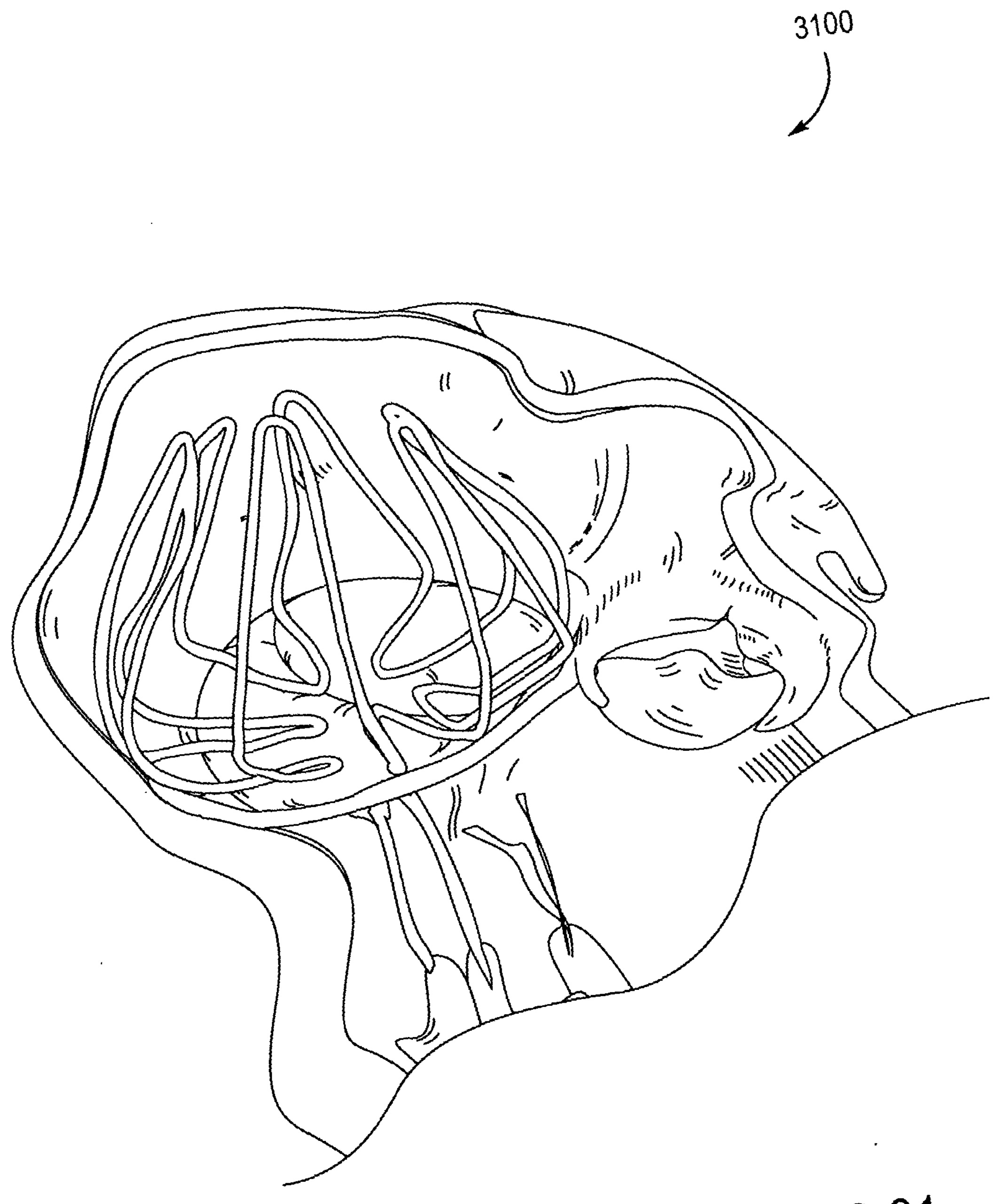


FIG 31

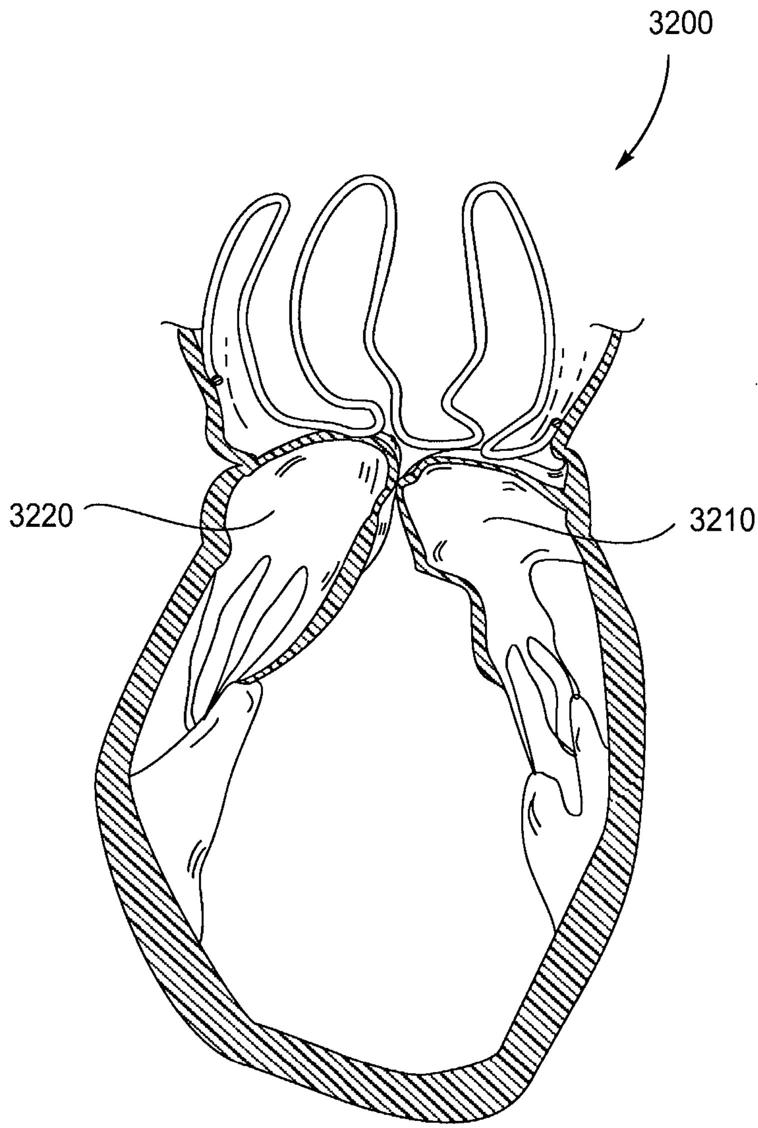


FIG 32

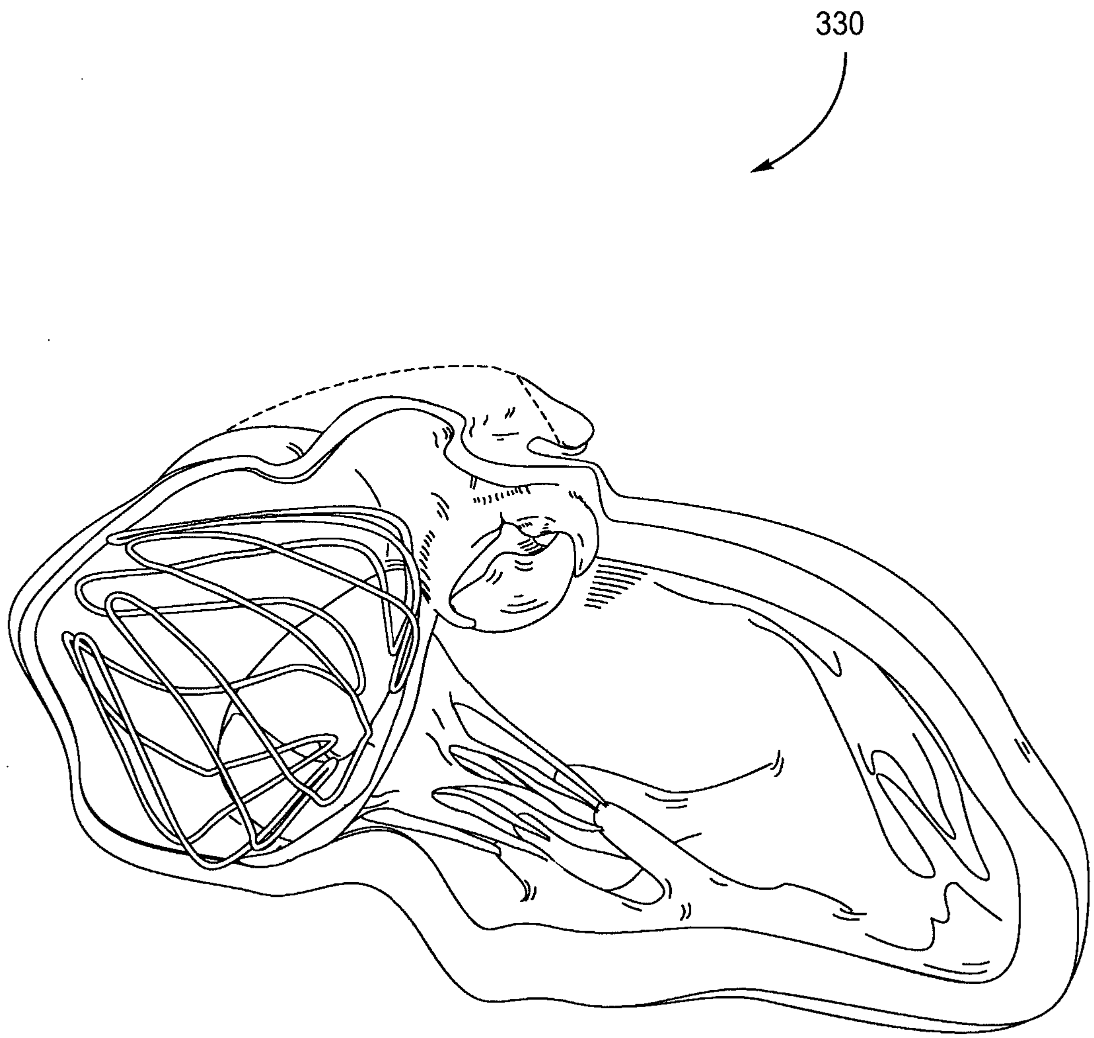


FIG 33

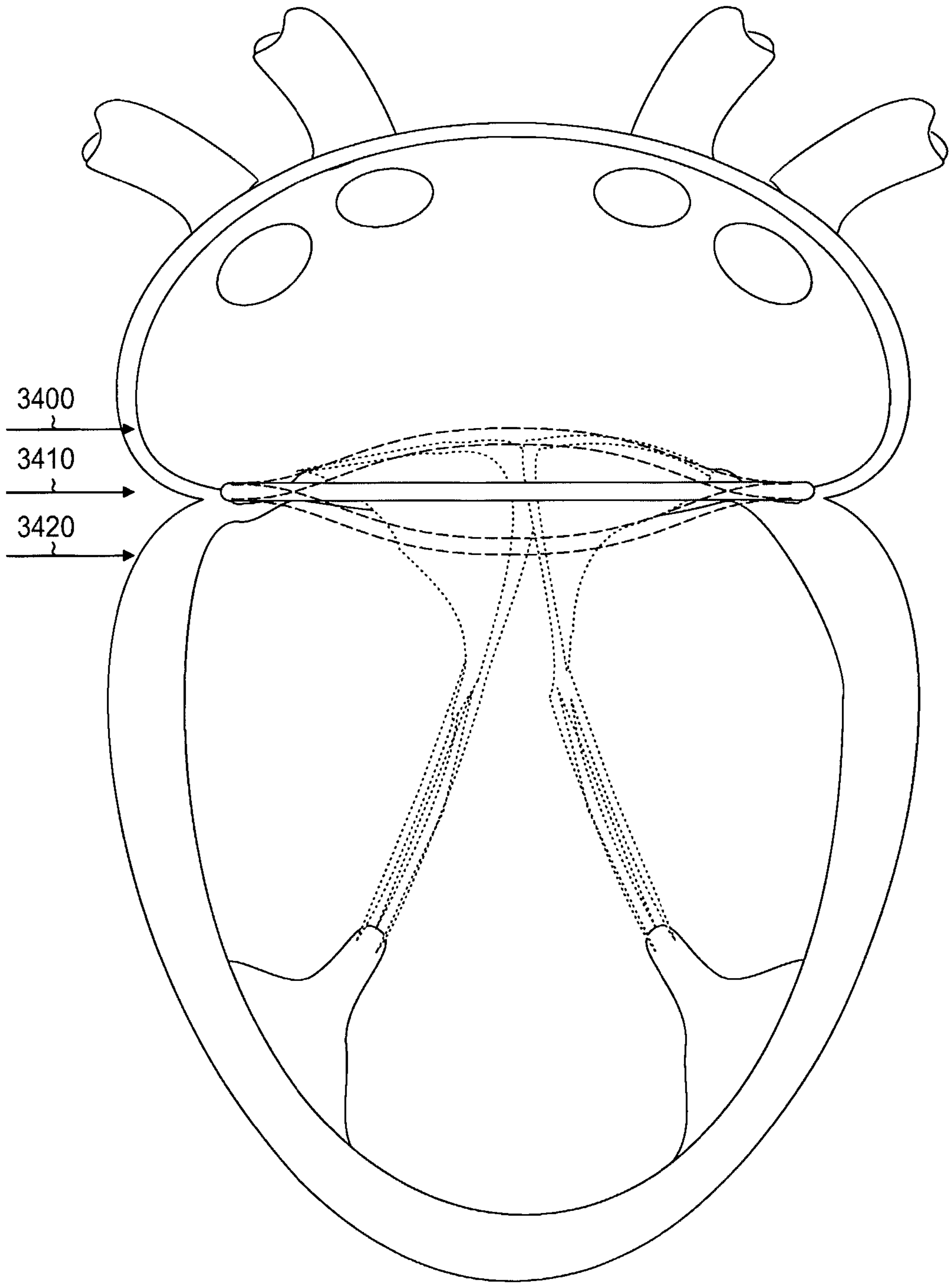


FIG 34

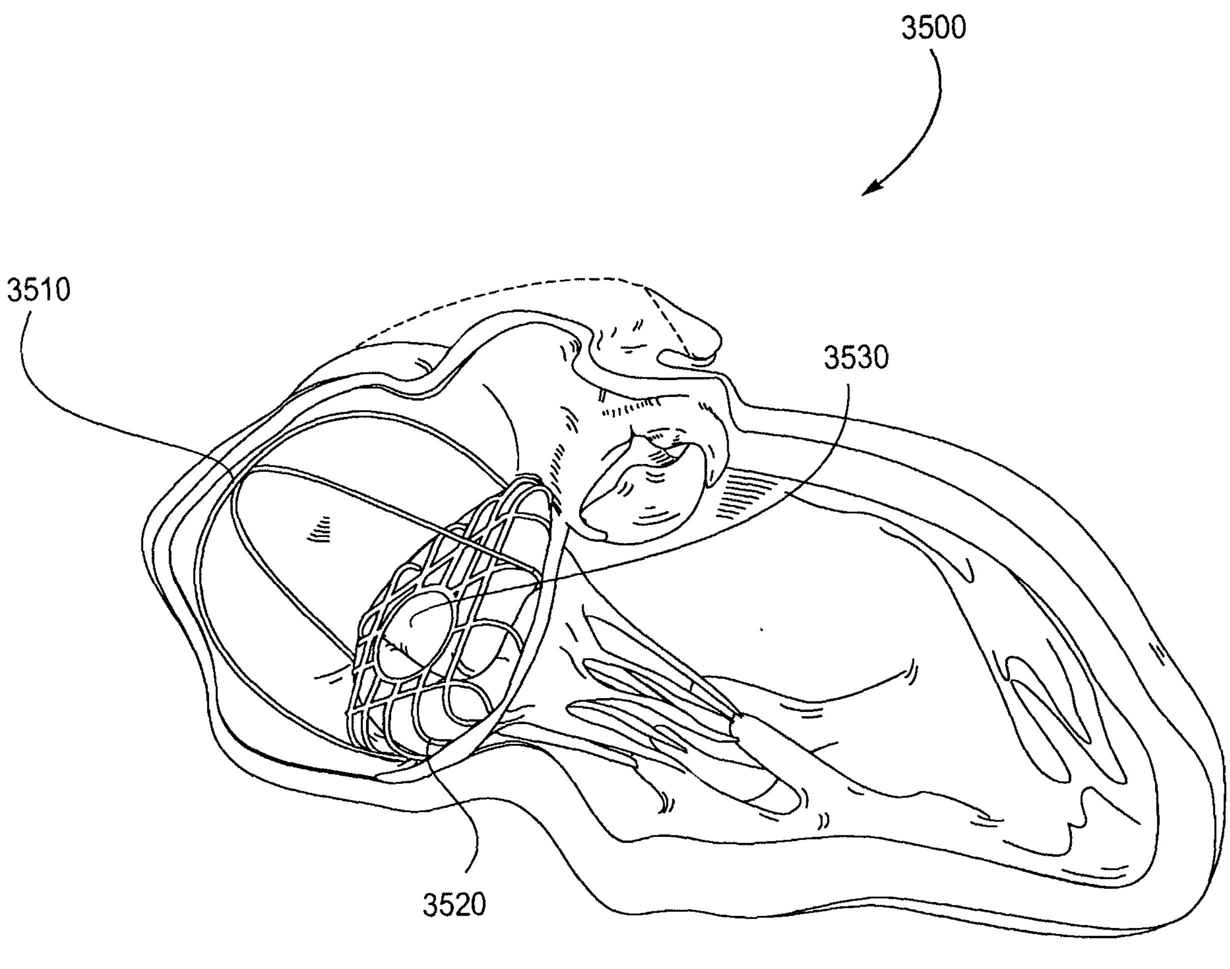
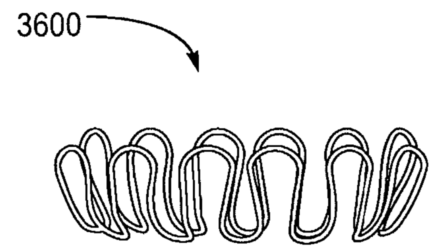


FIG 35



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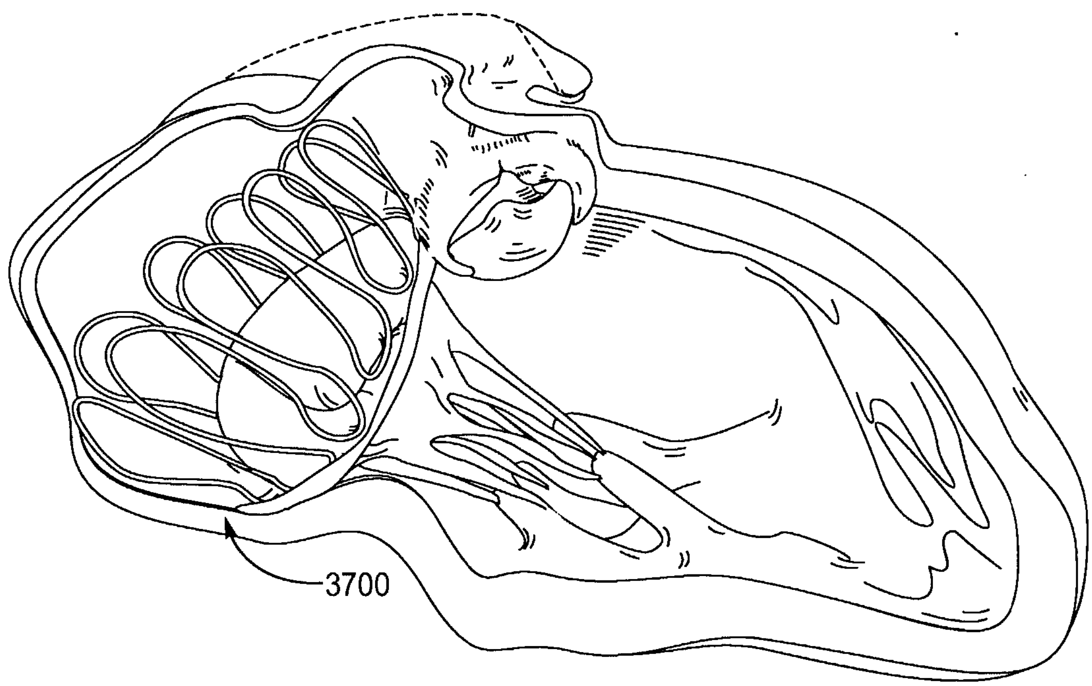
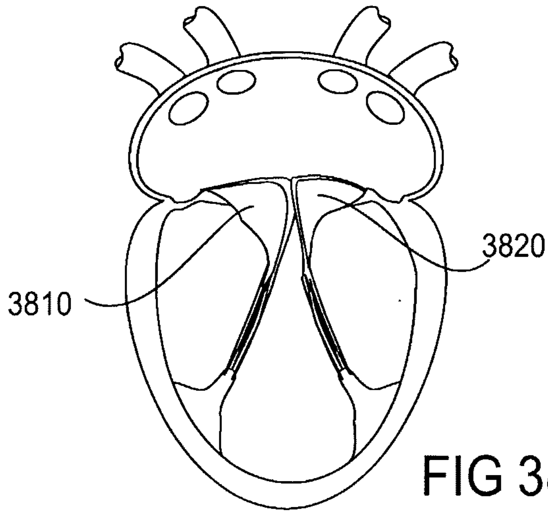


FIG 37



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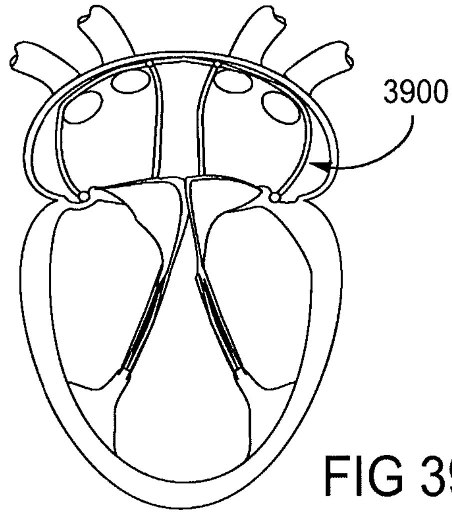

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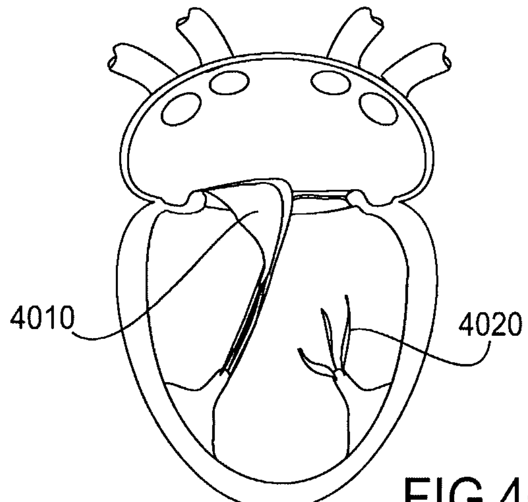

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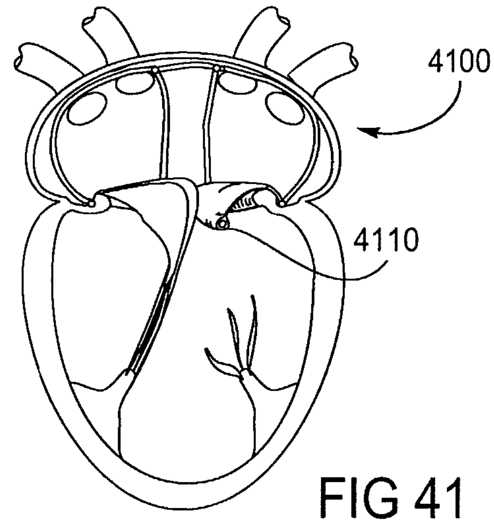

FIG 41

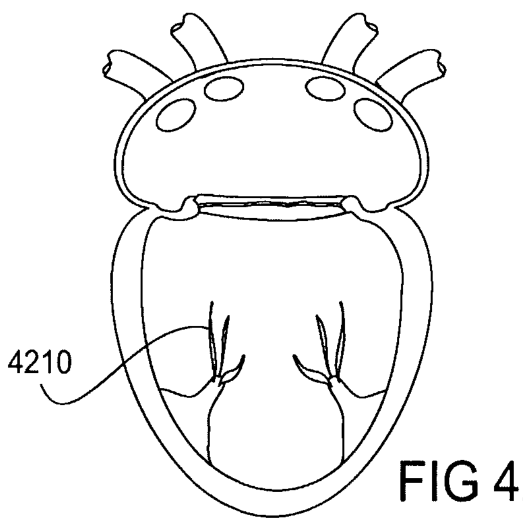

FIG 42

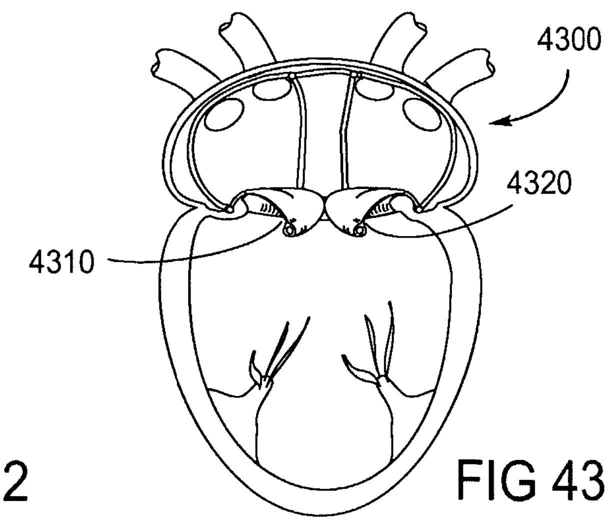

FIG 43